# Invitation to Bid: Alabama Medicaid Pharmacy Clinical Support

RESPONSE TO ITB # 08-X-2192281



PREPARED FOR STATE OF THE ALABAMA MEDICAID AGENCY



## **COPY**

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### 1 Transmittal Letter

Monday, May 19, 2008

State of Alabama Division of Purchasing RSA Union Building 100 N. Union Street Suite 192 Montgomery, Alabama 36130-2401

Dear Mr. Arant,

On behalf of Goold Health Systems, Inc. (GHS), I am pleased to present our response to the Invitation to Bid (ITB) # 08-X-2192281. As Chief Executive Officer, I will serve as the primary contact for this proposal and any subsequent contract negotiations.

GHS is a leader in pharmacy claims management, combining clinical expertise with some of the best national savings from our managed programs. We support the Pharmacy and Therapeutics (P&T) Committees for the State Medicaid Agencies in Iowa, Maine and West Virginia and are eager to bring our experience to Alabama's P&T Committee to improve upon the services and savings already in place.

Although not specifically requested in this ITB, I also wanted to mention that GHS administers the Sovereign State Drug Consortium (SSDC), a multi-state rebate pool that allows member states to gain the benefit of "pooled" lives for Supplemental Rebate purposes while maintaining the autonomy of their Preferred Drug Lists. Please let me know if you would like to discuss the possibility of joining the SSDC with you and how it could further enhance Alabama's savings and leverage the supplemental rebate knowledge of the six (6) states presently in the pool.

In response to ITB requirement 4.2, GHS provides the following

- a. As instructed, we have included one (1) original and five (5) copies of our ITB response printed on recycled paper and have also included a CD containing the file in MS Word 97–2003 format;
- b. We have not attached any addenda to our ITB response;
- Goold Health Systems, Inc. (GHS) is the sole contractor and is the legal name
  of the corporation submitting this proposal (we also do business as (d/b/a)
  "GHS Data Management");
- d. GHS is a company based in Maine but is now licensed to conduct business in the State of Alabama (License F/C 939-262);
- e. GHS operates in full compliance with Affirmative Action and Equal Employment Opportunity regulations that confirms that the bidder does not





discriminate in its employment practices with regard to race, color, religion, age (except as provided by law), sex, marital status, developmental disability, political affiliation, national origin, or handicap, and complies with all applicable provisions of Public Law 101-336, Americans with Disabilities Act;

- f. GHS acknowledges and agrees to all of the rights of the Alabama Medicaid Agency contained in the provisions of this ITB;
- g. GHS arrived at our proposed prices for this proposal without consultation, communication, or agreement with any bidder or competitor for this procurement;
- h. As CEO, I am the duly authorized representative and attest that GHS has in no way entered into any arrangement or agreement with any bidder or competitor which could lessen or destroy free competition in awarding the contract sought by the attached proposal;
- i. Unless required by law, GHS will not knowingly disclose the prices quoted, directly or indirectly, prior to award of the contract, to any other bidder or to any competitor;
- GHS has not and will not make any attempt to induce any other person or firm to withhold or submit a proposal for the purposes of restricting competition;
- k. As CEO, I am authorized to make decisions on behalf of the bidder's organization as to the prices quoted;
- 1. GHS has not employed anyone, other than a bona fide employee working solely for GHS, in soliciting or securing this contract;
- m. GHS affirms that that no person or agency has been employed or retained to solicit or secure the proposed contract based on an agreement or understanding for a commission, percentage, brokerage, or contingent fee; and
- n. Per GHS corporate policy 100.11, we maintain a drug-free workplace and perform pre-employment drug testing of employees.

Please contact me should you have any questions or need additional information. Thank you for this opportunity to provide you with our ideas.

Sincerely,

James A. Clair Chief Executive Officer Goold Health Systems, Inc. 45 Commerce Drive PO Box 1090 Augusta, Maine 04332-1090 207.622.7153 207.242.2715 (cell) jclair@ghsinc.com (email) 207.623.5125 (fax)





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# 3 Executive Summary

Goold Health Systems (GHS) brings over 34 years of Medicaid Pharmacy experience to Alabama Medicaid Agency's Pharmacy and Therapeutics (P&T) Committee solution. This includes 34 years of Pharmacy Benefits Services Administration (PBSA), 15 years of electronic Point of Sale (POS) claims processing and over 5 years of clinical pharmacy experience in Preferred Drug List (PDL) development, P&T Committee support, Supplemental Rebate (SR) negotiation, and Prior Authorization (PA) operations. We also serve as the multi-state pool vendor for the Sovereign States Drug Consortium consisting of the States of Iowa, Maine, Vermont, and Utah, West Virginia, and Wyoming.

GHS is fully capable and experienced in providing support to P&T Committees. We currently support the P&T Committees of Iowa, Maine, and West Virginia by providing objective, balanced explanations of the clinical and economic considerations in developing their PDLs. Our doctors, pharmacists, and other clinical experts are available to attend these meetings to provide valuable clinical information that ultimately guides Committee decisions.

We recognize that a strong, successful program is contingent upon a dedicated and supportive P&T Committee. Committee members become increasingly valuable over time. It takes a considerable, sustained effort to cultivate the knowledge requisite for P&T Committee members. The proper analysis of drug utilization data is exacting and complicated because of the idiosyncrasies of pharmacy benefit programs. Experienced members are a treasured commodity and treated accordingly. New members will be given introductory materials such as sample reports, definitions, and bylaws. We will always meet with new members prior to their first Committee session to walk them through the program goals, procedures, methodologies, and reports.

We also solicit information regarding any utilization analysis, study, or reporting preferences the Committee may have interest in exploring. It has been our experience that pursuing ideas of mutual interest is extremely beneficial to the long-term success of a State's PDL. It is essential to stimulate and maintain the intellectual interest of every P&T Committee member. Taking the time and effort to provide accurate and relevant data can greatly increase the confidence of the Committee members and empower them to reach the best conclusions.

Efficient application of the Preferred Drug List (PDL) is an area of excellence for GHS. Our system has been built to offer the maximum amount of functionality to our State Medicaid agency clients as possible. A highly intelligent and flexible system reduces both administrative costs and provider burdens while optimizing net savings for clients. GHS considers the PDL to be one of the most important aspects of a quality Pharmacy Benefit Services Administration (PBSA) system. A





carefully designed PDL, in combination with PAs and supplemental drug rebates, allows state Medicaid programs to realize significant cost savings without sacrificing clinical efficacy.

GHS has operated a PDL for Maine since 2003 and for Iowa since 2004. By the end of the first year of the PDL we designed in Maine, the net cost per member per month had been reduced by 5%. By the end of year two, with a fully deployed PDL, the net savings had increased to 11.7%. Despite inflationary pressures and utilization increases, the net cost per member at the end of 2005 (pre-PartD) was lower than it was in the year 2000. Our PDL effectively reset net costs per member for the State back five years. GHS firmly believes that we can provide the same level of savings to the State of Alabama.

Although there is a wide array of efficiencies available to capture Medicaid drug savings in our core operations, none of these measures alone can harness double-digit drug budget savings. The largest potential Medicaid pharmacy cost savings opportunity for the near future requires the successful integration of a PDL with PA and the Supplemental Rebates that accompany the PDL / PA process.

GHS' staff will provide support and research that will enable Alabama to operate an educated and informed P&T Committee. As we have done in the states of Iowa, Maine, and West Virginia, we will assist the Committee in enhancing its PDL in a way that will provide savings to Alabama Medicaid's drug budget. We look forward to assisting the State of Alabama in operating its P&T Committee.

Representing the Sovereign States Drug Consortium (SSDC) multi-state pool, GHS can negotiate the most advantageous contracts for the preferred drugs already listed on an SSDC member's PDL. We can also seek to provide a number of potentially superior contracts for drugs not on a PDL if an SSDC member and its P&T Committee are in favor of accepting. Although the pool negotiates prices and conditions, each state within the SSDC determines the composition of its own PDL, choosing which contracts to accept and which to reject. If Alabama opts to join the SSDC, it will retain complete PDL autonomy. Participation in the SSDC pool will allow Rebates to be solicited, negotiated, and collected at a nominal amount above and beyond this ITB. Although the price of membership in the pool is not included in our proposal, the advantages to joining far outweigh the nominal fees.

GHS has the tools in place to effectively and efficiently manage Alabama Medicaid's Hemophilia Audit Program. GHS is familiar with the challenges associated with specialty pharmacy services and intensive benefit management and its associated auditing. We have active and passive audit tools in place and experienced clinical staff able to monitor and assist Alabama's providers of clotting factors, while ensuring that the Hemophilia Standard of Care is continuously met.





# 4 Work Plan for Various Required Components

### ITB Section 4.3

GHS has the Medicaid, pharmacy and clinical expertise, resources and commitment to deliver all of the required work on time and according to specifications set by the Alabama Medicaid Agency. We successfully perform these duties for other states, will be using our experienced clinical and project management staff to ensure all requirements are met or exceeded, and will be augmenting our staff to ensure Alabama's specific needs are met.

In the following pages we outline our approach to the work plan in the major ITB sections. Although changes to the P&T Committee's schedule may emerge after contract award, we are basing this timeline upon Alabama's current P&T Committee schedule.

Date	Tasks
July 2008 Week 1	Meet with State staff and clarify schedule for first twelve months of contract. Present proposed schedule to Committee members to meet the needs of this ITB.
	Determine how much further the PDL can be expanded, which categories can be done by year's end and which should be staggered over CY 2009.
	Interview staff concerning their impressions of the current P&T Committee. It is very important to know who the key members are, what drug issues they tend/wish to focus on, how well they prepare in advance of meetings, how much they are influenced by outside organizations, and how long their remaining terms are.
	Review most recent PDL compliance data to identify any opportunities to maximize savings, including consideration of adding or subtracting preferred drugs. Review what needs to happen with key drugs and key categories to achieve success. This involves anticipating the data needs for the Committee and assisting the State in presenting recommendations in a manner that addresses their predictable concerns.
	Review current PA and step-care edits and compare with those from other states. Make recommendations to State for modifications.
	Seek approval for and/or make modifications to therapeutic class reviews.
	Present, review and seek authorization for cost analysis format.





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	Discuss current individual drug monograph format and determine which elements need to be emphasized / deemphasized or otherwise adjusted.
July 2008 Week 2	Make modifications as needed to deliverables discussed during first week as noted above.
	Finalize templates for all approved methodologies, reports, and working documents.
	Draft meeting agenda and public notice of August meeting, including scheduled drug classes for review, and submit to Medicaid for approval. Post agenda on Medicaid website no less than thirty days prior to meeting.*
	Notify manufacturers of August P&T meeting and provide them necessary information by certified mail return receipt no less than thirty (30) days prior to the meeting.*
July 2008	Assist Medicaid with optimal approaches for obtaining P&T support.
Week 4	Work with manufacturers approved for presentation at the August P&T meeting.
	At least two weeks before meeting, mail approved review packets to P&T Committee members, including all manufacturer correspondence.*
	At least two weeks before meeting, mail approved review packets to Medicaid, including all manufacturer correspondence, by CD, hard copy, and email. *
	*Actual dates may need to be adjusted during the initial transition period based on the agenda and the actual contract sign date.
August	Meet with any new Committee members.
2008	P&T Committee Meeting held.
	Submit meeting minutes to Medicaid for approval within two weeks of meeting.
	Send final copy of minutes within one week of Medicaid's approval of draft minutes.
September 2008	Draft meeting agenda and public notice of November meeting, including scheduled drug classes for review, and submit to Medicaid for approval. Post agenda on Medicaid website no less than thirty days prior to meeting.
	Notify manufacturers of November P&T meeting and provide them necessary information by certified mail return receipt no less than thirty (30) days prior to the meeting.
October 2008	Work with manufacturers approved for presentation at the November P&T meeting.
	At least two weeks before meeting, mail approved review packets to P&T Committee members, including all manufacturer correspondence.  At least two weeks before meeting, mail approved review packets to Medicaid, including all manufacturer correspondence, by CD, hard
	copy, and email.





November	Meet with any new Committee members.				
2008	P&T Committee Meeting held.				
	Submit meeting minutes to Medicaid for approval within two weeks of				
	meeting.				
	Send final copy of minutes within one week of Medicaid's approval of				
	draft minutes.				
December	Draft meeting agenda and public notice of February meeting, including				
2008	scheduled drug classes for review, and submit to Medicaid for approval.				
	Post agenda on Medicaid website no less than thirty days prior to				
	meeting.				
	Notify manufacturers of February P&T meeting and provide them				
	necessary information by certified mail return receipt no less than				
-	thirty (30) days prior to the meeting.				
January	Work with manufacturers approved for presentation at the February				
2009	P&T meeting.				
	At least two weeks before meeting, mail approved review packets to				
	P&T Committee members, including all manufacturer correspondence.				
	At least two weeks before meeting, mail approved review packets to Medicaid, including all manufacturer correspondence, by CD, hard				
	copy, and email.				
February					
February Meet with any new Committee members.  P&T Committee Meeting held.					
2000	Submit meeting minutes to Medicaid for approval within two weeks of				
	meeting.				
	Send final copy of minutes within one week of Medicaid's approval of				
	draft minutes.				
March	Draft meeting agenda and public notice of May meeting, including				
2009	scheduled drug classes for review, and submit to Medicaid for approval.				
	Post agenda on Medicaid website no less than thirty days prior to				
	meeting.				
	Notify manufacturers of May P&T meeting and provide them necessary				
	information by certified mail return receipt no less than thirty (30)				
	days prior to the meeting.				
April 2009	Work with manufacturers approved for presentation at the May P&T				
	meeting.				
	At least two weeks before meeting, mail approved review packets to				
	P&T Committee members, including all manufacturer correspondence.				
At least two weeks before meeting, mail approved review pace Medicaid, including all manufacturer correspondence, by CD					
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May 2009	Meet with any new Committee members.				
	P&T Committee Meeting held.				
	Submit meeting minutes to Medicaid for approval within two weeks of				
	meeting.				





	Send final copy of minutes within one week of Medicaid's approval of			
	draft minutes.			
June 2009	Draft meeting agenda and public notice of August meeting, including scheduled drug classes for review, and submit to Medicaid for approval. Post agenda on Medicaid website no less than thirty days prior to meeting.			
	Notify manufacturers of May P&T meeting and provide them necessary			
	information by certified mail return receipt no less than thirty (30)			
	days prior to the meeting.			
July 2009	Work with manufacturers approved for presentation at the August P&T meeting.			
	At least two weeks before meeting, mail approved review packets to			
	P&T Committee members, including all manufacturer correspondence.			
	At least two weeks before meeting, mail approved review packets to			
	Medicaid, including all manufacturer correspondence, by CD, hard			
	copy, and email.			





### 5 Approach to Administrative Responsibilities

### ITB Section 2.0 Scope of Work Overview

Goold Health Systems will provide Clinical Pharmacy Support to the Alabama Medicaid Agency as identified in ITB sections 2.1, 2.2, 2.3, and 2.5. GHS is poised to support the specific needs of Alabama Medicaid's P&T Committee, PDL, and Hemophilia Audit Program with flexible and adaptable solutions.

### ITB Section 2.1 Pharmacy Program Clinical Support

### Pharmacy and Therapeutic (P&T) Committee

### Clinical Information and Reviews

ITB 2.1 #1. Provide clinical information through the performance of clinical reviews of targeted classes or sub-classes of drugs to the Medicaid Pharmacy and Therapeutics (P&T) Committee and provide recommendations for inclusion/exclusion of reviewed drugs on the Medicaid Preferred Drug List. Review information provided to the P&T Committee shall be based on all relevant peer reviewed literature and studies, evidence based medicine and national guidelines. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

GHS will provide the Alabama Medicaid Agency with clinical reviews of therapeutic categories for review by their P&T Committee. We currently provide therapeutic class reviews for several of our Sovereign State Drug Consortium (SSDC) member states, including Iowa, Maine, Utah, Vermont, and West Virginia.

GHS' clinical and pharmaceutical staff provides a high-level analysis to compare the safety and efficacy of drugs within targeted therapy classes. Our staff is experienced in performing these analyses for several Preferred Drug Lists (PDLs) and will provide the same level of service to Alabama. It is of the utmost importance to make the P&T Committee aware of all clinically significant positive and negative drug attributes that could potentially affect the health outcomes of its members.

It is our overall belief that a PDL needs to provide a selection of preferred drugs that allows primary care physicians to care for the majority of their patients with minimal Prior Authorization (PA) requests being necessary. The driving force for or against recommending PDL placement is the drug's unique clinical contribution. Each state's P&T Committee must primarily rely on evidence-based guidelines, rather than clinical experience, expert opinions, professional relationships, pathophysiology, community standards, publications, or other sources, to determine the value of this contribution.





Evidence-based guidelines are instrumental to the ultimate success of the PDL. An increasing number of reputable medical journals have formally adopted the standard of reporting only on evidence-based medicine. As such, there is no longer any shortage of evidence-based guidelines upon which to build a solid foundation for a PDL. Although incomplete in scope, the bi-annual Clinical Evidence, published by the British Medical Journal, is a superior and heavily used resource for substrate data. It specifically aims to provide the raw material necessary for P&T Committees to form independent and unbiased opinions, rather than providing the specific recommendations themselves. Other information resources used include, but are not limited to, the Cochrane Library, ACP Journal Club, Evidence-Based Medicine, Evidence-Based Mental Health, and the Journal of Family Practice.

The goal of the clinical monographs and analysis is to assist Committee members in arriving at a rational assessment of what drugs represent the best value. If a drug offers a uniquely positive value, then it must be given an advantaged position on the PDL, unless the unique characteristic is only necessary for a minority of the population. When the characteristic is only necessary for a minority of the population, the drug may safely be reserved for those with a medical need as documented through (PA). The secret to influencing Committees successfully is to highlight and emphasize the key attributes of a drug that will enable them to arrive at the same conclusion as GHS' clinical staff and Alabama Medicaid's pharmacy program administrators.

Medical care decisions are increasingly being made on research-based evidence rather than on expert opinion or clinical experience alone. There are a plethora of nationally recognized scales to rate clinical studies. We could certainly continue to use what is currently in place if that is satisfactory to Medicaid. The rating system used by the Oregon Evidence Based Practice Center is very rigorous but not overly simple. Systematic reviews represent a rigorous method of compiling scientific evidence to answer questions regarding healthcare issues of treatment, diagnosis, or preventive services. Systematic reviews attempt to limit bias by the comprehensiveness and reproducibility of the search for and selection of articles for review. They also assess the methodological quality of the included studies and evaluate the overall strength of that body of evidence. Systematic reviews and technology assessments increasingly form the basis for making individual and policy-level healthcare decisions.

We would choose, if acceptable to Alabama, a rating system that meets the criteria espoused by the Agency for Healthcare Research and Quality (AHRQ). AHRQ has been the foremost Federal agency providing research support and policy guidance in health services research. AHRQ has provided guidance as to "best practices" in the field of rating clinical evidence. Based on their recommendations, our preference would be to use a system that is as simple as possible while meeting all of the AHRQ requirements for completeness. Many of the existing rating taxonomies already confuse many providers. Medicaid programs are primarily concerned with paying for the delivery of care and not with clinical research. We would therefore





want to adopt a rating system that is primarily concerned with patient oriented outcomes that measure changes in morbidity or mortality, as opposed to disease oriented outcomes that may or may not reflect improvements in patient outcomes. A good recent example of a disease oriented outcome that was not useful concerns the Vytorin study measuring changes in intima media thickness by ultrasound.

Considering the need to balance a thorough, valid, and fair rating system with a requirement for ease of application and comprehension, we would lean toward a grading system widely used in many primary care scientific journals known as SORT. SORT is a Strength of Recommendation Taxonomy that heavily weighs systematic reviews and randomized controlled trials. This taxonomy for rating the strength of a recommendation addresses the three key elements identified in the AHRQ report: quality, quantity, and consistency of evidence. This grading scale can be applied and understood by providers with varying degrees of expertise in evidence-based medicine and clinical epidemiology, and interpreted by physicians with little or no formal training in these areas. Please see an example of a SORT diagram on the following page in **Figure 1**. We believe this taxonomy addresses the issue of patient-oriented evidence versus disease-oriented evidence explicitly and is consistent with the information mastery framework proposed by Slawson and Shaughnessy, two very well known experts in the field.





Strength of ecommendation D	efinition		
Re Re	ecommendation based on consistent and ecommendation based on inconsistent of ecommendation based on consensus, us studies of diagnosis, treatment, preventi	or limited-quality patient-oriented evi- ual practice, opinion, disease-oriente	dence.*
	e to determine whether a study measuring to rinconsistent between studies.	ng patient-oriented outcomes is of g	ood or limited quality, and whether
Study quality	Diagnosis	Treatment/prevention/screening	Prognosis
Level 1—good-quality patient-oriented evidence	Validated clinical decision rule SR/meta-analysis of high-quality studies High-quality diagnostic cohort study†	SR/meta-analysis of RCTs with consistent findings High-quality individual RCT\$ All-or-none study§	SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up
Level 2—limited-qual patient-oriented evidence	ity Unvalidated clinical decision rule SR/meta-analysis of lower-quality studies or studies with inconsistent findings Lower-quality diagnostic cohort study or diagnostic case-control study§	SR/meta-analysis of lower-quality clinical trials or of studies with inconsistent findings Lower-quality clinical trial‡ Cohort study Case-control study	SR/meta-analysis of lower-quality cohort studies or with inconsistent results Retrospective cohort study or prospective cohort study with poor follow-up Case-control study Case series
Level 3—other evidence		ns from bench research, usual practi ogic outcomes only), or case series f	
Consistency across stud			
If noonsistent Co	lost studies found similar or at least coh- or high-quality and up-to-date systematic is onsiderable variation among study findin or high-quality and up-to-date systematic is favor of the recommendation	reviews or meta-analyses exist, they ngs and lack of coherence	support the recommendation

Figure 1 SORT diagram.

ITB 2.1 #2. Provide clinical information through the performance of clinical reviews to the Medicaid P&T Committee of drugs new to the market as well as drugs that the P&T Committee believes should be re-evaluated. Provide recommendations for inclusion/exclusion of reviewed drugs on the Medicaid Preferred Drug List. Review information provided to the P&T Committee shall be based on all peer reviewed literature and studies, evidence based medicine and national guidelines. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

GHS will provide clinical information through the performance of clinical reviews to the Medicaid P&T Committee of new drugs and drugs that the P&T Committee wishes to have re-evaluated. GHS will provide recommendations for inclusion / exclusion on the Preferred Drug List. Using a nationally recognized scale, GHS will rate each study or report that is presented to the Committee. GHS will choose a





suitable rating scale and consult with Medicaid upon its implementation upon contract award.

In evaluating the clinical literature pertaining to drugs under consideration for a PDL, we prefer to reference meticulously designed studies. When the effectiveness of a drug is tested, we prefer randomized, double-blinded, placebo-controlled trials. Assessing whether a substance is related to the development of an illness is best-studied using cases control design. Determining the outcome of a particular disease is best served with a longitudinal cohort study. P&T Committees (or other drug use subcommittees) use a formal clinical evaluation trial checklist to assist in reviewing relevant literature. This tool allows scoring on a number of characteristics including

- Population studied (inclusion / exclusion criteria);
- Treatments compared (biopharmaceutics);
- Experimental design detail (controls, randomized);
- Data collection (reproducible);
- Bias control (blinding);
- Results (measures, drop outs); and
- Data analysis (statistical tests, clinically meaningful).

Although we consider all of these different data sources and reviews to be valuable, we prefer to use condensed versions of the superior drug class reviews performed by the Oregon Evidence-Based Practice Center as the centerpiece for PDL considerations, as far as they are available. We then create and provide customized drug monographs and analyses to Committees, according to a state's specifications. For drug class reviews not yet addressed by the Oregon Evidence-Based Practice Center, a similarly structured meta-analysis is conducted. We follow the same procedure in refreshing the Oregon program reviews when significant new drugs arrive that were not originally considered. The only drawback with the Oregon reviews is that they provide far more details than most Committee members have time to digest. GHS will provide Alabama P&T members with a sensible distillation of the available data that is most relevant to the decisions that the Committee needs to make. As in the previous question, we would use the SORT system (or an equivalent approved by Alabama) to initially rate new drugs or classes reviewed out of the ordinary cycle. Figure 2 on the following page describes the general flow of the SORT algorithm.





### Strength of Recommendation Based on a Body of Evidence

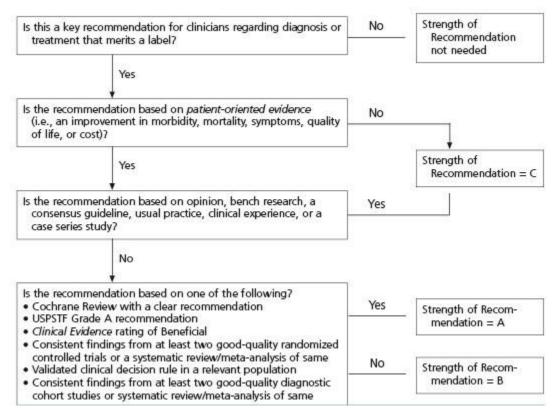


Figure 2 Flow of SORT Algorithm (American Family Physician)

GHS realizes that the P&T Committee will not have clinical expertise that deals with every therapeutic drug class. Therefore, we will facilitate the use of clinical subject matter experts. We provide the same service for our Maine program, and we find that this relieves not only the Committee from the burden of making decisions in areas beyond their specialty areas, but it gives answers to recipients and manufacturers who may question a clinical PDL decision.

In addition to providing subject matter experts, GHS thinks the selection of P&T Committee members has a great impact on the probability of the success of the PDL. Where and when possible, we would like to be involved in the selection process. GHS has analyzed and thereby acquired extensive knowledge of and experience with the other state Medicaid formularies. It is desirable that most Committee members have demonstrable experience in P&T related areas. It is questionable for a dentist—who presumably prescribes on a limited basis in the analgesic and antibiotic drug categories—to occupy one of the positions on a nine member P&T Committee. We recommend soliciting providers who are participating in or have actively participated on insurance company (HMO/state) or hospital P&T or Drug Utilization Review (DUR) committees.





ITB 2.1 #3. Recommend inclusion/exclusion of drugs to be considered in clinical reviews for P&T meetings based on AHFS or other classification, including but not limited to FDB coding.

Using AHFS or a similar classification (that includes FDB coding at minimum), GHS will recommend inclusion / exclusion of drugs considered in clinical reviews for P&T meetings.

GHS will provide clinical pharmacists and physicians to review therapeutic drug classes including new medications and indications. Our experts will provide recommendations regarding changes to the PDL and PA criteria. We provide the same service in other states and find that it greatly assists the P&T Committee in making responsible and timely decisions.

It is essential to continue analyzing relevant, timely clinical trial data, including updates on efficacy, safety, and added indications or patient populations. The P&T Committee needs to focus on the most important essentials of a drug to maintain PDL therapeutic classes including the following elements:

- Significant, clinically positive drug characteristics, especially if unique to class:
- Significant, clinically negative drug characteristics, especially if unique to class:
- Whether a drug was added only to receive a better offer on another drug; and
- What financial effect a drug will have on a PDL class if it is preferred or non-preferred.

Since Alabama has a well-established PDL, the primary operational concerns are now the annual negotiations and the interim drug considerations between Committee meetings. When a new drug (or form, strength, etc.) enters the market, Medicaid needs to adopt a preliminary status. Consider the following scenarios:

# 1. Therapeutic classes of drugs already reviewed by the P&T Committee:

In both Maine and Iowa, new drug entities (including new generics), and new drug product dosage forms of existing drug entities (in therapeutic classes already reviewed by the P&T Committees) are identified weekly and immediately coded as "Non-preferred-Prior Authorization required" until presented at the next quarterly scheduled P&T / Formulary Committee meeting of each state. The exception is new National Drug Codes (NDCs) for increased strengths of drugs already under contract. These can be automatically preferred under a contract amendment extension. These PA restrictions will continue through the review process, including while Committee recommendations are being made, and lasting until Medicaid makes a final determination.





# 2. Therapeutic classes of drugs not yet reviewed by the P&T Committee:

In Iowa, new drug entities in therapeutic classes not yet reviewed by the P&T Committee will remain payable, in effect preferred by default, until the therapeutic class is discussed. Once this review occurs for the class, the non-preferred default policy will apply to subsequent new drug entries. In Maine, new drug entities in therapeutic classes not yet reviewed by the P&T Committee are subject to a six-month moratorium and are coded as non-preferred, Prior Authorization required, until the therapeutic class is discussed and decided upon. The exception to this policy occurs during the annual supplemental rebate negotiation when all drugs currently available on the market are reviewed and rated concurrently.

### 3. Exceptions to the non-preferred default policy for new PDL drugs:

There are two major potential exceptions to Iowa's non-preferred default policy for new PDL drugs and to Maine's six-month moratorium:

- If a new medication is classified as a priority drug by the FDA, the States may indicate that such a drug is preferred until the drug is reviewed by the P&T Committee at the next scheduled meeting.
- The States may decide to designate a new drug as "draft preferred," and provide immediate access and increased therapeutic choice to physicians until the drug is reviewed by the P&T Committee at the next scheduled meeting if a new drug is:
  - Therapeutically equivalent or superior to existing preferred or nonpreferred choices;
  - As safe or safer than existing preferred or non-preferred choices;
     and
  - Less expensive, based net cost adjusted for all rebates, than all existing preferred choices.

### 4. Existing PDL Drugs:

Although these states discourage Supplemental Rebate offers on existing PDL drugs between annual bidding periods, they may entertain such bids and may accept them if:

- The offer is determined to represent significant, additional savings; and
- The offer would replace:
  - A delinquent manufacturer's preferred product;
  - A preferred drug pulled from the marketplace; or
  - A preferred drug significantly restricted by the FDA.





This interim preferred status remains in effect until the drug is reviewed by the P&T Committee at the next scheduled meeting. We will gladly modify any of these procedures to comply with the State's established processes or wishes.

In summary, we will provide timely reviews and recommendations, utilizing the AHFS and /or FDB classification systems, to Medicaid and the P&T Committee regarding new drugs, new indications, new safety issues, and negative studies both for the scheduled Committee meetings and for any interim drug decisions.

ITB 2.1 #4. Support the continued development and operation of the Medicaid Preferred Drug Program by providing current clinical research for review by the P&T Committee as well as providing qualified staff to present information to the P&T Committee.

GHS will provide all of the support services to the Alabama P&T Committee as we presently provide in West Virginia, Maine, and Iowa. Our pharmacists and other clinical experts are available to attend these meetings as requested and to provide valuable clinical information that ultimately influences Committee decisions.

GHS will provide the clinical, logistical and administrative support needed to perform its duties concerning the Pharmaceuticals and Therapeutics Committee. This will include facilitating meetings, recording meeting minutes, and providing any related data and/or analytical reports, including cost information.

Our typical approach involves a low-key approach while remaining flexible and maximizing the use of resources already at hand. The State of Alabama has had a successful PDL in place for several years now, and Medicaid already has many administrators and Committee members with extensive experience in this type of enterprise. Our approach is based on the belief that the Committee will usually make the best decision when it believes it has all the necessary information at hand. Nevertheless, Committees can at times be overwhelmed and even paralyzed with extensive therapeutic class reviews so it is often very important to know which points to focus on or refocus on in order to exercise influence.

We feel it is very worthwhile to learn the individual strengths of each Committee member. Some members have more time to do background research and homework than others do. Some are strongly evidence-based in their deliberations and some lean much more toward personal experience or the "art" of medicine. Some are opinion leaders on the Committee and others are followers. You can see predictable voting blocs over time on many issues. Members often vary widely in terms of their initial attraction toward new drugs. Over time, each Committee develops a personality. Who is present and who is absent can exert a tremendous effect on discussion and voting. It is our practice to consider all of these factors and to shape our approach to the Committee accordingly.

It is important to know what the pressure points will be on particular drugs or drug categories before allowing the Committee to motion for a vote. Ninety-nine percent





of the time, Committee acceptance of recommendations is desirable. In order to attain this goal, we must carefully anticipate what each member will need to vote in favor of the drug. Discussing how we think each member of the Committee will vote is a predictive exercise that helps us determine whether our recommendation is likely to be accepted and whether we should have several potential compromise positions ready (such as age limits or therapy exceptions). We recognize the importance of preparation and thorough background research on both clinical and utilization issues pertinent to drugs or drug classes under current discussion.

ITB 2.1 #5. Draft an agenda and meeting informational packets to include ballots for Pharmacy and Therapeutics (P&T) Committee meetings with Medicaid's approval. Draft materials are to be sent to Medicaid via electronic format and must be approved by Medicaid. A timeline for all drafts should be approved by Medicaid for each P&T review and must be followed by the Contractor.

GHS will draft an agenda and informational packets including ballots for the P&T Committee. After contract award, GHS will develop a timeline for all P&T Committee materials. We prefer to deliver materials 30 days prior to a P&T meeting. We have found that this gives the Committee members adequate time to review and digest the complex analysis. We would work with Medicaid to develop and approve all agenda items and P&T Committee material.

ITB 2.1 #6. Mail approved materials (informational packets, meeting agenda, etc) to all P&T members and necessary Medicaid staff. The materials are to be sent by Contractor via overnight mail and must be postmarked at least (2) two weeks prior to the meeting. There are currently nine (9) members of the P&T Committee. In addition, Medicaid requires ten (10) copies of the materials (a total of 19 hard copies will be needed). Copies for Medicaid staff may be directed to PDL Administrator, Pharmacy Services. Meeting materials must also be supplied to Medicaid in electronic format for posting to the Medicaid web site. Versions should be sent to Medicaid on CD, hard copies and via email.

We will overnight mail all copies of the materials to Committee members and Medicaid staff. In West Virginia we currently mail packets including therapeutic class reviews, drug monographs, meeting agenda, meeting minutes, and other relevant materials. We send copies to the Committee as well as copies to the State. The materials are presented to the Committee in hard copy form as well as electronically. We will also email copies of all material to the State. If Medicaid wishes, we can also arrange to have designated materials posted for public review.

ITB 2.1 #7. Provide clinical research, data and reviews to the P&T Committee and/or Medicaid regarding preferred drug reviews and drugs to be considered for prior authorization, overrides, or coverage issues as requested by Medicaid or the P&T Committee. Also, rate each study or report that is presented to support recommendations. The rating is to be based on a nationally recognized scale (the contractor may pick the one that is most appropriate) which indicates the strength of the evidence for validity, clinical appropriateness, etc.

GHS will provide clinical research, data, and reviews to the P&T Committee and/or Medicaid regarding preferred drug reviews and drugs to be considered for Prior





Authorization, overrides, or coverage issues as requested by Medicaid or the P&T Committee. GHS will also rate each study or report that is presented to support recommendations using our previously chosen and approved scale to access for validity and clinical appropriateness, among other things. As described in our responses to ITB Questions 2.1 #1 and #2, we will use the SORT system (or alternative if designated by Alabama) to indicate the strength of evidence across the multiple dimensions denoted by Medicaid. The materials will be presented in as succinct a format as possible, subject to approval by Medicaid.

GHS will also assist Medicaid in creating and implementing PA, overrides, and coverage issues as requested. We have developed extensive systems employing these techniques in both Maine and Iowa to support their respective pharmacy benefit programs. Therefore, we are experienced in developing step therapy and PA criteria to be integrated into the pharmacy claims adjudication process.

One of the first tasks we perform is to review a state's PA criteria and compare them to those of other states, especially the SSDC states. Knowing whether the criteria are looser, stricter, or equivalent than others helps us to project success (savings) and refine criteria efficacy.

GHS' PDL overrides, intelligent automatic edits, and step therapy verifications reduce the frequency of Prior Authorization submissions and generally keep physicians happy by reducing unnecessary paperwork. If the sole requirement for access to a non-preferred drug is failure of one or two preferred drugs, then the ideal solution is to have the claims processor look for preferred drug trials of a specified duration within a specified timeframe. If the criteria are met, the claim is paid and no PA is required for the member. If the PDL has step-care requirements, the step-care orders can be enforced by the claims processor. This saves all involved time, effort, and money. Generally, the fewer PAs that are needed, the less resistance there is to the PDL. We developed all of these criteria. You will also see many references to existing step-care edits in the PDL, including

- ACEI trial or diabetes drugs in profile prior to ARB use
- Metformin and sulfonylureas prior to thiazolidinedione use
- Fluoxetine first for children before other antidepressants
- Maximal dose of a potent statin prior to Zetia ®

Prior Authorization is a costly and resource intensive strategy that must be judiciously applied. It is expensive to operate and tests the patience of providers. Whenever feasible, it is preferable to have an ultra-efficient adjudication system apply the PDL criteria.





ITB 2.1 #8. Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for drugs specified by the P&T Committee and/or Medicaid.

GHS will monitor state and national trends in prescribing and dispensing patterns regarding the need for drugs specified by the P&T Committee and Medicaid. GHS has extensive experience in Prospective Drug Utilization Review (ProDUR) and Retrospective Drug Utilization Review (RetroDUR). By monitoring national and state trends and comparing that data with Alabama providers' prescribing patterns, we can provide timely analytical material to the Committee and Medicaid. We will monitor for atypical usage patterns of both preferred and non-preferred drugs. We will as a matter of routine, flag all rapidly increasing or decreasing drugs on the basis of both utilization and cost, so that Medicaid will be able to fashion responses in a timely manner. Often this involves being alert for off-label activity but the other aspect concerns quality of care. We can create and run reports for Alabama Medicaid that examine whether standards of care are being met and if certain diseases are becoming more prevalent. As one example, we can follow the incidence and prevalence of diabetes, especially in the pediatric population. We can describe the drug treatment preferences and the extent of polydrug therapy. We can integrate the medical claims data if desired and examine hemoglobin A1C testing frequency and examine how frequently home blood glucose monitoring is performed. We can examine the trend over long periods and make comparisons on some of these measures across other states.

ITB 2.1 #9. Provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner.

GHS will provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner. Alabama Medicaid needs a reliable support system to provide accurate responses to inquiries sent over many media; our clinical team can do just that.

GHS' assigned project manager and clinical pharmacist, Chad Bissell, Pharm.D., will be available to respond to any questions. Our Medical Director, Dr. Tim Clifford; our Associate Medical Director, Dr. Laureen Biczak; and our Director of Pharmacy Programs, Laurie Roscoe, R.PH., are all available to provide additional clinical expertise.

### Committee and Meetings

ITB 2.1 #10. Provide overview of clinical review packet information for each AHFS class reviewed to the P&T members at the Committee meetings.

GHS will provide the clinical review packet information overview for each AHFS class reviewed to the P&T members at the Committee meetings. The materials will be presented in a format agreeable to Medicaid. We will work very hard to keep the size manageable by emphasizing clarity and quality over quantity.





ITB 2.1 #11. Act as the recording secretary of all P&T Committee meetings and provide detailed and comprehensive minutes to Medicaid within (2) two weeks after the meeting for approval. A final copy is to be sent to Medicaid for sign-off upon completion and must be received by Medicaid within one week of receipt of approval by Medicaid.

GHS will act as the recording secretary of all P&T Committee meetings and provide detailed and comprehensive minutes to Medicaid for approval within (2) two weeks after the meeting. A final copy will be sent to Medicaid for sign-off upon completion and must be received by Medicaid within one week of receipt of approval by Medicaid. We will make any corrections to the minutes and publish the approved version on the website.

For Iowa, Maine, and West Virginia, we record, review, edit, and circulate draft minutes. After the approval of the draft minutes with any corrections, an approved version is sent to members and Medicaid and is then posted on the website. We will work with Medicaid to record accurate and thorough minutes.

ITB 2.1 #12. Provide a written summary of P&T Meeting minutes for Alabama Medicaid's DUR Board.

GHS will provide the Alabama's Medicaid DUR Board a summarized version of the P&T Committee's minutes as required. This will be done according to the timeline specified by Medicaid.

ITB 2.1 #13. Notify members of P&T Committee of meetings in coordination with Medicaid.

GHS will notify P&T Committee members of meeting dates in coordination with Medicaid and according to all Medicaid guidelines and timelines. This will be done in the format(s) specified by Medicaid.

ITB 2.1 #14. Receive, review and mail all qualified manufacturer comments to P&T members and Medicaid. Manufacturers are to be notified of any documents containing inappropriate information such as cost so that they can make arrangements for pickup.

GHS will receive, review, and mail all qualified manufacturer comments to P&T members and Medicaid. Manufacturers will be notified of any documents containing inappropriate information such as cost so that they can make arrangements for pickup. GHS keeps a record of all negotiations with manufacturers on behalf of Alabama Medicaid.

ITB 2.1 #15. Coordinate all requests for oral presentations by manufacturers at P&T meetings to include receipt of requests, receipt and review of presentation summaries, written record of sign in by presenters at meetings, receipt and review of handouts at P&T meetings and distribution to Medicaid and members.

GHS will coordinate all requests for oral presentations by manufacturers at P&T meetings to include receipt of requests, receipt, and review of presentation summaries, written record of sign in by presenters at meetings, receipt and review





of handouts at P&T meetings, and distribution to Medicaid and members. GHS currently provides this service for the SSDC member states.

ITB 2.1 #16. Notify manufacturers of upcoming P&T reviews and maintain database of manufacturer contact information sheets.

GHS will notify manufacturers of upcoming P&T reviews and maintain a database of manufacturer contact information sheets. This is a service GHS currently provides for the SSDC member states.

ITB 2.1 #17. Provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.

GHS will provide electronic versions of public notices and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline established by Medicaid. GHS currently provides this service to Iowa, Maine, and West Virginia for their P&T Committees.

ITB 2.1 #18. Send written notification to P&T members whose terms are expiring.

GHS will send written notice to P&T members whose terms are expiring per Medicaid policy. We assume that we will be given standard language to be used supplied by Medicaid.

ITB 2.1 #19. Send written notification to new members selected for the P&T Committee.

GHS will send written notice to newly selected P&T members per Medicaid policy and will assist in conducting orientations for new members to the Committee (See 2.21 below). Again, we assume that there is standard language already available for such notifications.

ITB 2.1 #20. Maintain a listing of Committee members and send an electronic version to Medicaid annually or upon update.

GHS will maintain a listing of Committee members and will send an electronic version of that list to Medicaid annually and upon update of Committee membership. This will probably also contain their appointment dates and tentative term expiration dates.

ITB 2.1 #21. Conduct an orientation with all new members prior to first meeting to provide an orientation to the Committee. These meetings are to be conducted with a designated Medicaid staff member.

GHS will provide orientation to new members of the P&T Committee prior to first meeting with the assistance of a designated Medicaid staff member. New members are given introductory materials such as sample reports, definitions, and the bylaws. GHS will meet with new members prior to their first P&T Committee session to walk them through the program goals, procedures, and reports.





We believe P&T Committee members to be an extremely valuable resource and treat them accordingly. A new member must be carefully integrated into the existing team so as to give him or her the tools needed for the job, while not overwhelming the individual with a multitude of extraneous data. Interest and participation is maintained by discovering a new member's specific motivating factors and finding commonality within the Committee.

ITB 2.1 #22. Provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.

GHS will provide an electronic version of public notice of meeting and drug classes scheduled for review to Medicaid for posting to web site in accordance with timeline.

ITB 2.1 #23. Respond to clinical appeals as related to the reviews for the P&T Committee meeting for the PDL. Responses should include any concerns or issues in the appeal from the manufacturer concerning the drug, information regarding any studies or clinical information that the manufacturer has presented, and give reason why it was or was not included in the review and why or why it does not change the recommendation. A final summary paragraph needs to state if the original recommendation presented in the review should stand as is or if it needs to be amended. It is the responsibility of the Contractor to respond to any appeals within the designated timeframe regarding information that the Contractor has presented even after the contract has expired.

GHS is prepared to draft responses to inquiries from providers and interested parties regarding the PDL. We are also prepared to accept inquiries by phone, mail, email, or fax. We will draft these responses with the urgency assigned to it by Medicaid. We will only directly respond to these parties when and as authorized by Alabama Medicaid. We have drafted many responses for other state governors, commissioners, Medicaid Directors, pharmacy program administrators, legislators, and other officials. Some of these clinical appeals may legitimately lead to a desire on our part to have the Committee reexamine their initial decision. We will comply with Medicaid's timeframe and acknowledge our responsibilities that extend beyond contract expiration.

### Preferred Drug Program and Listings (PDL)

ITB 2.1 #24. Compile a list for Medicaid approval of all products scheduled for PDL review and maintain all PDL lists by utilizing Medicaid's Decision Support System (DSS) and FDB and AHFS classes.

GHS will compile a list for Medicaid approval of all products scheduled for PDL review and maintain all PDL lists by utilizing Medicaid's Decision Support System (DSS) and FDB and AHFS classes. We will adopt Alabama's current format and protocol if desired. We assume that there will be two different but parallel timelines and processes here. At the most immediate level, interim PDL recommendations will be needed for every drug appearing in the weekly drug file. Medicaid will then need a periodic summary, varying according to the meeting schedule, of how all drugs are being formally recommended for PDL treatment according to clinical





desirability and financial attributes that will form the basis for presentations to the P&T Committee. There may be a sub-classification based on whether the new drug is a brand or generic, or just a new strength or formulation. It might be important for us to recognize if a new drug should be subject to an existing PDL class clinical Prior Authorization requirement or a diagnostic code intervention.

ITB 2.1 #25. Recommend classes or sub-classes of drugs to Medicaid to be included in the Preferred Drug Program.

GHS will recommend classes or sub-classes to Medicaid to be included in the Preferred Drug Program. Alabama Medicaid will benefit from GHS' experience managing the preferred drug programs for the states of Iowa, Maine, and West Virginia.

The potential savings must be worthwhile considering the potential administrative expenses, including Prior Authorization. Efficient design and application of the PDL is an area of excellence for GHS. Our PDL management system has been designed to offer the maximum amount of functionality possible. We have learned that a highly intelligent and flexible system reduces both administrative costs and provider burdens while optimizing net savings. We will do our best to assist Medicaid in the further development and management of its PDL. We have designed different PDLs tailored to the unique needs of each state.

Alabama Medicaid can always save more money within its PDL; so the question is really how much discomfort they and their providers are willing to endure to obtain additional savings. This is no small matter so any additional administrative burden needs to be carefully weighed and then mitigated. Next, we must determine how much further the PDL can be expanded and over what time span. It is beneficial to then ascertain from Medicaid what has and has not worked well over the past few years and interview staff concerning their impressions of current drug Committee deliberations and apparent biases. After a state has established a PDL, it has made a long-term commitment to its basic structure. There is only so much change that can be tolerated from year to year. When a state joins a pool, such as the SSDC, a certain amount of realignment is mutually beneficial. Again, only a small to moderate amount of PDL changes can be tolerated, so changes are reserved for the largest dollar values. Therefore, the method of developing a new PDL for a state is vastly different from supporting a PDL-experienced state like Alabama.

The methodology for expanding the PDL is decided as much by Medicaid as it is by GHS. This is a collaborative process. Although we have our own ideas on how to approach the initial design of each PDL category, we benefit greatly from Medicaid's input. The expansion of the PDL, including the potential redesign of certain categories, must reflect the considerations and will of Alabama Medicaid.

The most important aspect of deciding how far to expand the PDL largely depends on how satisfying the results have been so far. We need to assess what the true net





costs and savings have been to date and to know what has been working well and what has not. Depending on the level of resistance within the legislative and policy structures, we can provide varying levels of increased savings. We designed a more complete and aggressive PDL in Maine than in Iowa because Maine's savings needs dictated doing so. Our "method" in each state will vary depending on a state's specific fiscal needs.

It is our overall belief that a PDL needs to provide an ample enough selection of preferred drugs that allows primary care physicians to care for the majority of their patients without Prior Authorization requests being necessary on a daily basis. States want more savings, but they also need PDL stability. It never makes sense to chase short-term dollars. We all need to be looking several years down the line. States demand PDL efficiencies of scale and process to maximize savings, minimize overhead, and maintain or improve clinical effectiveness.

ITB 2.1 #26. Provide projected cost savings for classes/sub-classes recommended for review for the PDL based on past medical claims data.

This is one our special interests and an area of particular expertise. GHS will provide clinical information and saving analyses of specific drugs under review by the P&T Committee at least fourteen days prior to each Committee meeting. We will present estimated savings in a manner agreeable to Medicaid. This will involve estimations based on both current and projected utilization. Savings will be blended across all drugs within a category to keep estimations confidential if they are going to be used in public. If the analyses will be purely for internal consumption, then we can get true net costs down to the NDC level. We could also apply estimated costs to anticipated PAs in each class so that Medicaid and the Committee can consider the net return on investment of its PDL design. Depending on Medicaid's preference, we can present either a simple summary of estimated savings within each class, reflecting shifts in market share utilization, average blended net cost per unit, and SRs, or a more complex analysis. An initial simpler approach to help states examine PDL class design options might involve a spreadsheet analysis, like **Figure 3** on the following page, an analysis done for a client state on statins.





### **Cholesterol reducing agents**

Assı	ume
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Total volume/year	100,000
Ave. \$/unit pref generic	\$0.25
Ave. \$/unit pref brand (w SR)	\$1.50
Ave. \$/unit non-pref brand	\$2.00

#### **Scenario One- Maximize Generics**

	Total Units	Unit cost	Total Cost
Generic share	60,000	\$0.25	\$15,000.00
Brand share (no SR)	40,000	\$2.00	\$80,000.00
			\$95,000.00

### Scenario Two- Insert Preferred Brand between preferred generics and non-preferred brands

	Total Units	Unit cost	Total Cost
Generic share	60,000	\$0.25	\$15,000.00
Preferred Brand share (w SR)	30,000	\$1.50	\$45,000.00
Non-Preferred Brand share (w/o			
SR)	10,000	\$2.00	\$20,000.00
			\$80,000.00

### Scenario Three- One Preferred Brand co-preferred with preferred generics

	Total Units	Unit cost	Total Cost
Generic share	50,000	\$0.25	\$12,500.00
Preferred Brand share (w SR)	40,000	\$1.25	\$50,000.00
Non-Preferred Brand share (w/o			
SR)	10,000	\$2.00	\$20,000.00
			\$82,500.00

### Scenario Four- Two Preferred Brands co-preferred with preferred generics

	Total Units	Unit cost	Total Cost
Generic share	47,500	\$0.25	\$11,875.00
Preferred Brand share (w SR)	45,000	\$1.50	\$67,500.00
Non-Preferred Brand share (w/o			
SR)	7,500	\$2.00	\$15,000.00
			\$94,375.00

#### Scenario Five- No PDL

	Total Units	Unit cost	Total Cost
Generic share	30,000	\$0.25	\$7,500.00
Brand share (w/o SR)	70,000	\$2.00	\$140,000.00
			\$147.500.00

Figure 3 Example spreadsheet analysis on statins for PDL class design study.

In the more complex analysis, we use a predictive pricing approach to estimate the final budget impact of PDL decisions after accounting for all rebates, prescribing alterations, and offsetting administrative costs. We have attached the initial step of this methodology in **Figure 4** below. The first step involves analyzing whether a





specific PDL decision will result in less or more savings than another scenario. This requires us to make market share assumptions, then examine, and quantify the results. To do this, we use prior experiential claims data on similar drugs or drug classes that have already been incorporated within PDLs. In Figure 4, we model several assumptions on the statin class. We vary market shares and net unit costs to arrive at potential savings. We then compare the outcomes of these scenarios to projected and actual Lipitor net prices. The models are reviewed with the States to arrive at a best fit.

allive	at a best.	116.						
Exhibit IV c.								
Cholesterol	- HMG COA +							
/nhi	bitors		Baseline *		S cenario A	Scenario B	S cenario C	Scenario D
Pure Statins			No Mktshr Cha		No Mktshr Cha	No Mktshr Cha	Mktshr Cha	Mktshr Cha
			.,,	•	.,	.,		
Sim∨astatin								
	Avg Units/Scrip	t	30		30	30	30	30
	Avq Unit Cost		\$2.00		\$1.00	\$0.50	\$1.00	\$0.50
	Avg Script Co:	st	\$60.00		\$30.00	\$15.00	\$30.00	\$15.00
LIPITOR	1							
	Avg Units/Scrip	t	30		30	30	30	30
	Avg Unit Cost		\$2.20		\$2.20	\$2.20	\$2.20	\$2.20
	Avg Script Co:	SI	\$66.00		\$66.00	\$66.00	\$66.00	\$66.00
* 5								
* Baseline = Mai				1 1				
	Baseline Ma	arketShare	Baseline *		Marketshare Cost	Marketshare Cost	Marketshare Cost	Marketshare Cost
	Mktshr	Scripts						
Simvastatin	19.0%	6,974	19.0%	Mktshr %	19.0%	19.0%	66.9%	66.9%
			6,974	Scripts	6,974	6,974	24,607	24,607
			\$418,440	Mktshr Cost	\$209,220	\$104,610	\$738,215	\$369,107
LIPITOR	63.0%	23,147	63.0%	Mktshr %	63.0%	63.0%	15.0%	15.0%
			23,147	Scripts	23,147	23,147	5,514	5,514
			\$1,527,702	Mktshr Cost	\$1,527,702	\$1,527,702	\$363,914	\$363,914
			\$1,976,264		\$1,767,044	\$1,662,434	\$1,132,250	\$763,143
		'	Chang	e from Baseline	(\$209,220)	(\$313,830)	(\$844,014)	(\$1,213,121)
			Oriang					
				% chg	-10.59%	-15.88%	42.71%	-61.38%

Figure 4: Predictive pricing approach to estimate the final budget impact of PDL decisions.

Once we have this data, we take the same model and invert the drugs to model out non-preferred market share with respect to Prior Authorizations. Again, we look at experience when available to see how many PAs were generated and what percent were approved in order to determine what the loss rate will be. We then assign a value to each projected loss based on the net increased value of each non-preferred drug and in this case, whatever value you assign to the cost of performing a PA. The second step of the predictive model involves calculating the potential cost of the non-preferred drugs and the PA process. We perform this operation in two stages. First, there is the cost of the Prior Authorization component. This is derived from statistics gathered in states we serve:

PDL Drug Category A
Potential PA cost = (#PAs/Qtr) X (Assigned value of cost/PA)





The second component involves projecting the number of PA approvals and the increased net cost of the non-preferred drug relative to the net value of the preferred drug(s). This is based on actual data from states with the same or similar PDL structure.

### PDL category A

PA Approval rate (%) X (#PAs/Qtr) X (Difference in net cost between non-preferred-preferred drug)

We will now use an actual example from Maine using the Proton Pump Inhibitor (PPI) class to illustrate how this works. In Q1-2006 Nexium went from preferred to non-preferred.

- 1) Potential PA cost = (245 PAs) X (\$25/PA) = \$6,125/Qtr
- 2) Potential PA approval cost = (PPI = 55%) X (245 PAs) X (\$63/Rx) = \$8,489.25
- 3) Potential Total PA cost = \$14,614.25

The only other corrections needed to apply this to other states are to adjust for population differences between states and steady state lag. Steady state lag refers to the period between when a preferred drug becomes subject to PA and when the rate of PAs being submitted becomes steady. This rarely takes longer than one quarter.

This model was based on our experience with other Medicaid programs. We went through the process of estimating savings prior to each PDL decision, after each final PDL decision, and again after implementation. This approach is not perfect however, so we have persisted in our efforts to improve our projection accuracy over the past few years. Many categories can be projected extremely accurately because we have gone through several iterations of the process. We routinely provide to states a spreadsheet report showing pre-rebate savings, Supplemental Rebates, and post-rebate net savings along with associated administrative costs (including both developmental-implementation and operational) each quarter. An example of this summary spreadsheet is provided on the next page in **Figure 5**. We used sections of this model to previously explain how we estimate overall net savings retrospectively both within and across all PDL categories.





# Iowa Medicaid Net Savings in Q1 and Q2 CY2005



	Q1 CY2005	Q2 CY2005	Totals for Both Quarters
PA/PDL Savings:	\$2,596,895	\$3,545,165	\$6,142,060
Supplemental Rebate Savings:	\$ 4,235,192	\$4,364,408	\$8,599,600
Combined Savings:	\$ 6,832,087	\$7,909,573	\$14,741,660
Implementation Costs for 3 months:	\$168,966	\$168,966	\$337,931
Operational Costs for 3 months:	\$249,999	\$249,999	\$499,998
Total Costs for 3 months (Implementation Costs + Operational Costs):	\$418,965	\$418,965	\$837,929
State Share of Total Costs (50%)	\$209,482	\$209,482	\$418,965
State Savings (Combined Savings for Q1 CY2005 * .3636)	\$2,484,147	\$2,875,921	\$5,360,068
Net Savings (State Savings - State Share of Total Costs):	\$2,274,665	\$2,666,438	\$4,941,103

Figure 5 Iowa Medicaid Net Savings

Based on our experience, we have acquired a good sense of all the factors necessary to predict accurately. It is vital to know what percent of a population can successfully be maintained on two or three specific preferred drugs. Each category is different. Prior utilization data around the PDL and PAs must be mined to glean this information. It is also essential to know what percent of the population is already on the preferred and non-preferred agents. This is useful both for calculating successful switches and for estimating PA volume, a key component of administrative costs.

Although it may take more time, it is also very useful to determine who would already meet PA approval criteria by virtue of having already tried every preferred choice. This can lead to accurate savings discounts and to consideration of POS online "approvals." Any age or condition exclusions need to be factored in as well as implementation timelines. Exceptionally tight or demanding criteria that require testing or specialty consultations must have their associated costs included.

Administration costs including the PA and PDL contracts will be assimilated into the projections. We will also be able to provide some help in forecasting administrative fair hearing rates in the various PDL categories.





ITB 2.1 #27. Make recommendations to Medicaid regarding operational policy and procedures for the Preferred Drug Program and pharmacy program policy and procedures as they relate to the scope of work of this ITB. Contractor is expected to utilize its expertise in the scope of this ITB to identify procedures that may improve current Medicaid policy.

GHS will make recommendations to Medicaid regarding operational policy and procedures for the Preferred Drug Program and pharmacy program policy and procedures as they relate to the scope of work of this ITB. GHS will utilize our expertise to identify procedures that may improve current Medicaid policy. There are many ways of enhancing savings within the PDL by employing such techniques as maximizing dose consolidation, quantity limits, and day supply limits. Some states allow PDL rules to be overridden by Third Party Liability (TPL) claims (members with other insurance where Medicaid is the secondary payer) and this can lead to PDL abuse, such as stores submitting claims where the other insurer has supposedly paid pennies or a dollar on a non-preferred drug claim thus allowing the claim to bypass PDL PA requirements. PA criteria adjustments can have huge ramifications, so being aware of the other approaches is vital. Early refill abuse is another area that we have assisted client states in. Tightening up early refill thresholds, especially in controlled substances, can pay big dividends. Another monitoring opportunity concerns pharmacy returns and reversals. We routinely report on reversal rates and audit stores with suspiciously low figures. We would look forward to assisting Alabama Medicaid in updating and improving operational procedures and policies.

ITB 2.1 #28. Develop, maintain, and update internal and external criteria for those drugs that fall in the scope of the PDL, as well as when requested by Medicaid for those drugs currently on prior authorization that fall outside the scope of the PDL. All criteria must be approved by Medicaid.

GHS will develop, maintain, and update internal and external criteria for those drugs that fall in the scope of the PDL, as well as when requested by Medicaid for those drugs currently on Prior Authorization that fall outside the scope of the PDL. GHS will obtain Medicaid approval for all criteria. Studies, reviews, and guidelines are being constantly released. They are difficult to keep up with but vital to assure that the PDL rules remain current and rational. PDL and PA criteria need to be reassessed at least annually and whenever new evidence appears.

Many drugs residing outside of PDL managed classes may still require clinical Prior Authorizations to determine medical necessity. There is also the problem of non-rebatable drugs (like vigabatrin) being sought by medical providers for potentially life threatening conditions. The following scenarios may also require further action

- Drugs become unavailable due to shortages or discontinuation;
- New products and new forms enter the market and require prompt attention;
- Generics become available but are often financially unattractive initially;
- New FDA approved indications appear often and necessitate revisions of existing criteria;





- FDA warnings are released on drugs and corresponding alterations must be made in the PDL or in an unmanaged drug class;
- Significant price fluctuations; and
- Companies reneging on deals or not honoring the terms of existing contracts.

### **Drug Coverage Recommendations**

ITB 2.1 #29. Provide notification to Medicaid within one calendar week of First DataBank (FDB) notification of products new to the market that fall into a classification of drugs included in the scope of the Preferred Drug List or the Prior Authorization Program, override program, or coverage/non-coverage. Provide recommendations to include in review for PDL, Prior Authorization Program, override program, or coverage/non-coverage.

GHS will provide notification to Medicaid within one calendar week of First DataBank (FDB) notification of products new to the market that fall into a classification of drugs included in the scope of the Preferred Drug List or the Prior Authorization Program, override program, or coverage / non-coverage. We will provide recommendations to include in review for PDL, Prior Authorization Program, override program, or coverage / non-coverage. GHS currently performs this scope of work in West Virginia.

ITB 2.1 #30. Review FDB Clinical and Editorial highlights on a weekly basis and make recommendations to the Agency on any needed actions.

GHS will review FDB Clinical and Editorial highlights on a weekly basis and make recommendations to the Agency on any needed actions.

ITB 2.1 #31. Provide projected cost savings for potential edits/overrides/non-coverage for drugs and drugs classes that fall outside the scope of the PDL as requested by Medicaid.

GHS will project cost savings for potential drug benefit management interventions falling outside the current PDL scope. We will use the Alabama DSS in order to arrive at these savings models. We already perform this duty frequently in several states. We can predict savings from clinical Prior Authorizations, vary them according to the intensity of the proposed criteria, and project out several state fiscal years while making accommodations for changing state and federal shares. We can also build in adjustments for planned alterations in eligibility or benefit design. These projections can be updated over time and recalibrated so that future projections will become successively more accurate.

ITB 2.1 #32. Maintain and update the maximum unit list using methodology approved by Medicaid. This list should be updated on a routine basis according to a timeline approved by Medicaid. New drugs identified for the max unit list must be approved by or recommended by Medicaid. Currently, Medicaid max unit limits are based on FDB's GSN coding.

We will continuously maintain an up-to-date maximum quantity list. This is probably most efficiently done each week when the new drug file is reviewed and loaded, but we can do it whenever required by Medicaid. It is understood that Medicaid will make all final determinations in this matter of new drug status





assignments. We are familiar with the FDB Generic Sequence Number (GSN) coding system in working with several of our current clients.

ITB 2.1 #33. Maintain and update the covered nutritional list using methodology approved by Medicaid upon request.

GHS will maintain and update Alabama Medicaid's covered nutritional list using the approved methodology referenced above. We already perform this function for one of our Medicaid clients, including the responsibility for operating the associated Prior Authorizations. We are also familiar with interfacing with state WIC programs so that Medicaid only pays for truly essential resources not otherwise available through the WIC program. GHS will follow all CMS regulations as pertaining to nutritional lists.

ITB 2.1 #34. Recommend drugs, based on clinical information, to be considered for prior authorization, override, or coverage to Medicaid through the P&T Committee or the Agency that fall into the following categories:

Drugs with historical problems relative to physical and psychological dependency

GHS will identify drugs prone to potential abuse and develop recommendations for management that could involve PA, specific overrides, or coverage determinations for consideration by the P&T Committee and/or Alabama Medicaid. One example concerns fentanyl lollipops. Although it is a non-preferred drug by virtue of high cost, one client state required PA for all members, while another state allowed pharmacy overrides using cancer and hospice diagnostic code overrides.

Drugs used for non-FDA approved indications or whose use is not supported by appropriately conducted and published, peer-reviewed medical research

GHS will identify drugs subject to significant, poorly supported off-label usage and develop recommendations for management that could involve Prior Authorization, specific overrides, or coverage determinations for consideration by the P&T Committee and/or Alabama Medicaid. For example, one of our client states manages all branded anticonvulsants very aggressively. We had performed an audit that demonstrated a nearly 50% off-label usage rate several years ago. Many newer anticonvulsants were being used off-label for chronic pain and bipolar conditions, even though there was minimal good evidence and despite the availability of many treatments with FDA-approved indications and/or better published evidence. We also developed diagnostic code overrides and grandfathering requirements such that seizure patients had direct access to all covered products.

Drugs which require important diagnostic procedures be completed before the administration to maximize therapeutic benefits

GHS will identify drugs that require diagnostic due diligence prior to administration. Many more such drugs are being released onto the market each





year. Several of the HIV drugs including Selzentry<sup>TM</sup> fall into this category. Many of the new anti-cancer therapies are only of value in specifically targeted patients, so proper patient selection is crucial.

Drugs associated with special dosing, duration and/or administration requirements or considerations

GHS will identify drugs that require special dosing, duration, and/or administration requirements or other clinical considerations. There are drugs that are more difficult for a patient to self-administer than others. If the patient is not properly educated, then the medication may inadvertently be wasted or misused.

One example of a difficult to administer drug was Exubera<sup>®</sup>. Patients had great difficulty in becoming adept at using this inhalable insulin. Primary care doctors never became comfortable with it and therefore the drug died very quickly and was withdrawn from the market. Generally speaking, a state does not want its PDL to encourage the adoption of predictably problematic drugs like this. We also routinely make recommendations on dose optimization (consolidation or splitting). Some drugs have very dangerous drug-drug and/or drug-disease interactions and can benefit from a variety of soft or hard pharmacy claim edits. Certain drugs require chain of custody to ensure patient safety. Medicaid might only want to allow a specialty or home infusion pharmacy to directly dispense the drug to a patient, or they might allow a pharmacy to deliver the drug to a physician's office for administration in certain circumstances.

Drugs for which feedback is necessary to assist practitioners with treatment alternatives that may be just as effective, safe and less costly

GHS will develop methods that provide feedback to providers that encourage safe and more cost-effective alternatives. Preferred drug lists can incorporate step-edits that promote the use of the best available choice from a range of either preferred or non-preferred products. Educational newsletters and provider-specific mailings or other forms of intervention can be utilized. Educational campaigns can be sustained over time or periodically reintroduced to reach out to new providers.

Drugs for which over-the-counter alternatives exists and are covered or could be covered by Medicaid Drugs with high cost or supply problems

GHS already performs this function for several clients. We compare the Over the Counter (OTC) drug to available legend therapeutic alternatives in order to arrive at recommendations. We will confirm an OTC drug's rebate status and develop OTC State Maximum Allowable Cost (SMAC) recommendations. Recommendations will incorporate advice as to whether the OTC drug should be covered, if Prior Authorization or diagnostic codes should be required, and if only particular manufacturers will be preferred on the basis of rebates or guaranteed net offered to Medicaid. Drugs with exorbitant costs need to be identified and managed quickly. Draft interim PA criteria can be developed for immediate usage until the drug can





be formally reviewed. Supply problems can also require nearly instantaneous reactions in the PDL. We frequently need to identify the next best priced drug(s) or best clinical comparator when supply issues arise on preferred drugs.

Recent examples include needing to rapidly add preferred birth control pills when a Wyeth version suddenly became unavailable. Another variation on high cost is when a new manufacturer/labeler takes over an existing product. Inderal® LA had historically cost less than the generic Propranolol ER, because of high OBRA rebates, until this past year. The original manufacturer sold out to Akrimax, which then promptly raised the Average Wholesale Price (AWP) over 40%. This action finally made the generic "less expensive" than the brand, necessitating a rapid PDL switch from the brand to the generic. This seems to be happening more as manufacturers jettison their old brands with huge OBRA rebates, and the new labelers rapidly increase the AWP costs in order to overcome the Medicaid rebate drag.

# 2.1.1 Hemophilia Audit Program

GHS has extensive experience in Intensive Benefit Management, where we monitor and audit prescription utilization and dispensing patterns. In applying this know-how to Alabama's new Hemophilia Audit Program, GHS can establish monitoring guidelines to track compliance and standards of care guidelines per this ITB.

ITB 2.1.1 #1. Conduct, at minimum, bi-annual retrospective audits on providers of blood clotting factor to ensure compliance with minimum standards of care guidelines, reimbursement methodology and Medicaid and State billing and BOP policy, dispensed dose assay, 24-hour call emergency support service, appropriate staff, emergency delivery of blood clotting factor

GHS will conduct, at minimum, bi-annual retrospective audits on providers of blood clotting factor. These audits will ensure compliance with minimum standards of care guidelines as outlined in ITB Attachment I, reimbursement methodology, Medicaid and State billing, and BOP policy. GHS will audit and assess the Program's functionality in regards to dispensed dose assay, 24-hour call emergency support service, appropriate staff, and emergency delivery of blood clotting factor.

We have dealt with several of the leading national providers of specialty pharmacy and infusion therapy products. We can monitor the standard of care guidelines (such as World Federation of Hemophilia and the National Hemophilia Foundation) and ensure that the providers treat the condition effectively based on the patient's personal needs, medical condition, and therapy regimen.

We will coordinate and conduct the audits in an orderly and systematic manner in order to be certain that quality hemophilia/coagulation infusion therapy is always available in the most expedient and convenient way possible. We will confirm that contracted pharmacies have hemophilia trained pharmacists on staff; state-of-the-art IV compounding facilities that offer a wide range of product concentrations, including low-, mid-, and high-range assays; infusion therapy administration by





skilled registered nurses to optimize treatment benefits while minimizing life disruptions for the patient; 24-hour on-call nursing and pharmacy service; and 24/7 product/assay availability for emergencies. Our staff is aware of the latest medications and administration techniques necessary to ensure optimal oversight.

ITB 2.1.1 #2. Conduct, at minimum, bi-annual retrospective audits on hemophilia patient assessment and follow up, educational materials offered and monthly case management follow-up.

GHS will conduct, at minimum, bi-annual retrospective audits on hemophilia patient assessment and follow-up, educational materials offered, and monthly case management follow-up. The best hemophilia pharmacy providers offer experienced registered nurses specializing in hemophilia home infusion, comprehensive nursing assessments with full systems review, pediatric nurses on staff, continuity of care with the same nurse available for consecutive treatments, specialized line and catheter placement and maintenance, and counseling about medications, including side effects and an extensive array of print and web based educational resources to help patients understand hemophilia. The leading providers in this field can demonstrate reductions in units used (after age adjustments), hospitalizations, and preservation of joint function. The more rigorous the ongoing education and care management is, the larger the dividends returned in the way of improved healthcare outcomes and cost control.

ITB 2.1.1 #3. Conduct retrospective audits of notification of product recalls or withdrawals as needed or requested by Medicaid

GHS will conduct retrospective audits of notification of product recalls or withdrawals as needed or requested by Medicaid. GHS will access Medicaid's DSS to compare lot numbers of recalled or withdrawn medication and identify patients and pharmacies affected. Hospitals and prescribing doctors may need to be contacted to assist in recalling all dispensed medications.

ITB 2.1.1 #4. Conduct, at minimum, bi-annual retrospective audits of quantity of blood clotting factor dispensed, the amount billed and invoice pricing submitted to Alabama Medicaid

GHS will conduct, at minimum, bi-annual retrospective audits of quantity of blood clotting factor dispensed, the amount billed, and invoice pricing submitted to Alabama Medicaid. We will collect the direct price charged by the manufacturer for factor dispensed, all discounts, chargebacks, rebates received, and the actual acquisition cost paid for the factor. Supporting documentation will be sought along with an attestation that all pricing information is accurate.

ITB 2.1.1 #5. Notify participating pharmacies of auditing procedures, to include requesting required documentation needed.

GHS will notify participating pharmacies of auditing procedures, to include requesting required documentation needed. GHS currently provides a similar





auditing service to the States of Iowa, Maine, and West Virginia in managing their P&T Committees.

In addition to the pricing information described in the previous answer, we will carefully match up the quantities ordered by the physician with what was delivered either directly to the home or intermediary setting through another provider. The procedures will include checking the intended dose, range, and frequency. We will examine degree of severity and recent blood factor levels as available. GHS will confirm appropriateness of prophylactic patient selection and dosing levels. We will be alert for patterns indicating excessive wastage, which is not uncommon with hemophilia. In a prior audit, our staff has seen instances where a pharmacy has billed for emergency vials shipped but never logged as received and administered.

ITB 2.1.1 #6. Mail approved materials to hemophilia providers and necessary Medicaid staff. The materials are to be sent by Contractor via certified mail and must be postmarked at least 30 days prior to the audit.

GHS will mail approved materials to hemophilia providers and necessary Medicaid staff. The materials will be sent by GHS via certified mail and will be postmarked at least 30 days prior to the audit.

ITB 2.1.1 #7. Report the outcome of each provider audit to the designated Alabama Medicaid representative.

GHS will report the outcome of each provider audit to the designated Alabama Medicaid representative. We will create a report customized to the specifications of Medicaid. We will also create an annual report summarizing the evidence and actions taken resulting from the minimum biannual audits.

ITB 2.1.1 #8. Recommend to Alabama Medicaid's designated pharmacy staff those non-compliant pharmacy providers.

GHS will identify non-complaint pharmacy providers for Alabama Medicaid designated staff and develop recommendations for appropriate correction plans and specific follow-up measures. If helpful, we can create a specific report based on a hemophilia provider scorecard.

ITB 2.1.1 #9. Utilizing the Agency Decision Support System (DSS), identify hemophilia providers to be audited, detailed patient specific claim information, and blood clotting factor reimbursement information to be used in the auditing procedures.

GHS will use the Agency Decision Support System (DSS) to identify hemophilia providers that will be audited. We will integrate the detailed patient specific claim information and blood clotting factor reimbursement information to be used in the auditing procedures. Using this data we would recommend stratifying providers across several dimensions in order to flag unusual or higher "risk" characteristics. These might include outliers in units per member per month, cost per member per





month, and number of emergency bleeds per year. Hemophilia providers often do batch billings so the payments can lag substantially after actual dates of service. We will be mindful of this when analyzing specific time periods and selecting audit candidates.

ITB 2.1.1 #10. Draft audit procedures and hemophilia provider notifications. Draft materials are to be sent to Medicaid via electronic format and must be approved by Medicaid. A timeline for all drafts should be approved by Medicaid for each audit and must be followed by the Contractor. At the time of writing this ITB, the Agency has draft audit criteria for the Contractor to make recommendations before final approval.

Using Alabama Medicaid Agency's draft audit criteria and GHS' experience in pharmacy auditing, we will draft audit procedures and hemophilia provider notifications. GHS will submit electronic draft materials to Medicaid for review and approval and follow the timelines agreed upon by Medicaid.

GHS currently provides tamper evident auditing procedures in Maine where we perform weekly audits of 25% of pharmacies in the state. The pharmacies have a specified time to review the prescriptions for compliance with State law and respond to GHS where we provide reporting back to the State. We also provide Retrospective Drug Utilization Review (RetroDUR) in Maine to analyze prescribing patterns for narcotics, patient profiles, compliance issues, and antidepressant adherence. These programs give GHS a breadth of experience in auditing practices to help Alabama ensure compliance from patients and providers as well as an opportunity to find savings within the Hemophilia Audit Program.

ITB 2.1.1 #11. Provide a Hemophilia Audit Coordinator to conduct and oversee auditing procedures. This person shall have a deep understanding of hemophilia, blood clotting factor delivery, and prescriptions/orders for these drugs. The Hemophilia Audit Coordinator may also serve as the Clinical Pharmacist.

GHS will provide a Hemophilia Audit Coordinator to conduct and oversee auditing procedures. This person shall have a deep understanding of hemophilia, blood clotting factor delivery, and prescriptions/orders for these drugs. Although his/her primary expertise will be in hemophilia care, we would expect this person to be well versed in home infusion issues involving other common co-morbid illnesses such as hepatitis C. The overlap of these two diseases is considerable and a better coordinated care approach is desirable. GHS envisions this position to be fulfilled by either a newly hired Alabama clinical pharmacist (Pharm.D.) or a Registered Nurse with a background in hemophilia.

ITB 2.1.1 #12. Provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner.

GHS will provide clinical information and respond to questions from Medicaid designated Pharmacy staff in a timely and professional manner. It is understood





that the designated staff must be readily available during Alabama's designated working hours.

ITB 2.1.1 #13. Support the continued development and operation of the Medicaid Hemophilia Audit Program by providing current clinical research for review as well as providing qualified staff to present information to the fair hearing meetings held in Montgomery, AL.

GHS will support the continued development and operation of the Medicaid Hemophilia Audit Program by providing current clinical research for review as well as providing qualified staff to present information to the fair hearing meetings held in Montgomery, Alabama. We do understand that the standard of care for hemophilia continues to evolve and grow more complex. It is important that the State stay abreast of major developments and position itself at the leading edge of providing specialty care for its most vulnerable members. Some of the most relevant research concerns the pharmacoeconomics of specialty drug care management in insured populations.

Our staff perform a similar scope of work in Iowa, and our clinical teams in Augusta, Maine, will support the efforts of our Alabama staff clinical pharmacist and/or hemophilia audit coordinator.

ITB 2.1.1 #14. Provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for blood clotting factor specified by Medicaid.

GHS will provide clinical information and utilization data based on state and national trends in prescribing and dispensing patterns regarding the need for blood clotting factor specified by Medicaid. We have access to all of the publicly available Medicaid claims data from the Centers for Medicare & Medicaid Services (CMS) website. We routinely create normative data that can be used for comparisons between states. We also provide services to other Medicaid programs through the Sovereign States Drug Consortium, which allows data sharing between states when mutually beneficial.

#### 2.1.2 Reference Tools

GHS will provide current in-depth clinical information using the digital and printed media listed in the ITB.

# **ITB Section 2.2 Clinical Reviews**

GHS will provide recommendations for classes to review for the PDL based on AHFS classification, and any new drugs that are eligible for review in the scope of the PDL. The Agency will provide GHS with the approved AHFS classes and new drugs for review. GHS will provide Medicaid with a list of drugs from Medicaid's drug file that fall into those AHFS classifications, and add/delete drugs that fall into/out of the particular AHFS classification(s) along with documentation to





clinically support why those particular drugs need to be included / excluded from the review. GHS will also provide recommendations on how to group / sub-group single entity versus combination products, what drugs are brand versus generic, and OTC versus legend. The Agency will approve the first draft of the drug list and return to GHS as defined in a timeline approved by Medicaid for each respective review. GHS will provide the Agency with a "clean," approved, final drug list (to include all appropriate information as listed in Contractor Deliverables) as defined in a timeline approved by Medicaid for each respective review. GHS will obtain Medicaid approval prior to deviating from approved final list.

Reviews will be developed and presented according to the AHFS classification system unless specified by Medicaid. Reviews will be developed in a consistent format as agreed upon with Medicaid. Medicaid will approve the groups and subgroups by AHFS classification in which GHS intends to conduct and present the reviews. GHS will obtain Medicaid approval prior to deviating from the approved groupings and/or sub-groupings. All reviews will follow Medicaid policy.

Reviews will reference and discuss peer reviewed studies and publications relevant to the drugs under review. References will be included in the review packets. GHS will review and reference all pertinent studies and clinical literature. Supporting documentation will be available upon request by the P&T Committee or Medicaid. Also, GHS will rate each study or report that is presented to support recommendations. The rating will be based on a nationally recognized scale indicating the strength of the evidence for validity, clinical appropriateness, etc.

GHS will give an oral presentation of the reviews at the P&T Committee meeting. This presentation will be made by a clinical pharmacist who is fully versed with the information contained in the review and who is capable of entertaining questions from Committee members regarding findings and recommendations.

# **ITB Section 2.3 Contractor Deliverables**

GHS will provide all contract deliverables in a timely and professional manner in a format using a timeline approved by Medicaid. GHS has a proven history of meeting project goals on time or ahead of schedule, while providing exemplary customer service and clinical expertise.

### **P&T** Committee

#### Clinical Information and Reviews

ITB 2.3 #1. Provide a packet to P&T members and Medicaid staff to include, clinical reviews, agenda, table of contents, and ballots for P&T Committee meetings in electronic format and hard copy as described in Section 2.1, item(s) 4, 5, 6 of this ITB. Each clinical review packet should be contained in a three ring binder and should be labeled and paginated accordingly. The P&T Committee is required to meet a minimum of four times per year.

Prior to each of the four (or more) P&T Committee meetings, GHS will provide a packet to P&T members and Medicaid staff that includes clinical reviews, agenda,





table of contents, and ballots in electronic format and as hard copy in a labeled and paginated three-ring binder as described in ITB Section 2.1, items 4, 5, and 6.

ITB 2.3 #2. Provide queries, using Medicaid's DSS, for drug lists for clinical reviews upon Medicaid's request to include information deemed appropriate by Medicaid but not limited to: NDC, brand name, generic name, manufacturer, manufacturer labeler code, strength, dosage form, Alabama specific generic indicator, OTC versus legend indicator as described in Section 2.1, item(s) 3.

Using Alabama Medicaid's DSS, GHS will provide queries for drug lists for clinical reviews upon Medicaid's request to include information deemed appropriate by Medicaid but not limited to: NDC, brand name, generic name, manufacturer, manufacturer labeler code, strength, dosage form, Alabama specific generic indicator, and/or OTC versus legend indicator as described in ITB Section 2.1, item 23.

ITB 2.3 #3. Provide to Medicaid a response to clinical appeals on work conducted by the Contractor requested by manufacturers as a result of PDL or P&T reviews. These responses should be received by Medicaid within 30 days of the request. The response should contain clinical information to support the recommendation given by Contractor as described in Section 2.1, item(s) 23.

GHS will provide to Medicaid a response to clinical appeals on work conducted by GHS that was requested by manufacturers as a result of PDL or P&T reviews. These responses should be received by Medicaid within 30 days of the request. The response should contain clinical information to support GHS' recommendation as described in ITB Section 2.1, item 23.

### Committee and Meetings

ITB 2.3 #4. Provide written meeting notification to P&T members prior to mailing the review packet as defined in a timeline approved by Medicaid for each respective review as described in Section 2.1, item(s) 13.

GHS will provide written meeting notifications to P&T members as required by Medicaid as stated in ITB Section 2.1, item 13.

ITB 2.3 #5. Provide detailed minutes of P&T Committee meetings so that discussion, motions, amendments and recommendations are reflected accurately as described in Section 2.1, item(s) 11.

GHS will provide detailed minutes of P&T Committee meetings, reflecting accurately upon all discussion, motions, amendments, and recommendations as detailed in ITB Section 2.1, item 11.

ITB 2.3 #6. Provide a written P&T Committee update report for the Drug Utilization Review (DUR) Board as described in Section 2.1, item(s) 12. This information may be given in written format to Medicaid Contract Administrator. It should be a brief summary of activity and actions of the P&T Committee. The DUR Board meets a minimum of four times per year.





Upon approval of P&T Committee meeting minutes, GHS will provide a written update report containing a summary of the agenda and actions of each P&T Committee meeting as stated in ITB Section 2.1, item 12.

ITB 2.3 #7. Provide a Medicaid approved professional clinical representative to present oral presentations of clinical reviews at P&T Committee meetings as described in Section 2.1, item(s) 10.

GHS will provide a Medicaid approved professional clinical representative to present oral presentations of clinical reviews at P&T Committee meetings as described in ITB Section 2.1, item 10.

ITB 2.3 #8. Provide notice to manufacturers of upcoming reviews via certified mail return receipt requested; clinical reviews up to the time of the writing of this ITB averaged approximately 100 notices per meeting as described in Section 2.1, item(s) 15.

GHS will provide notice to manufacturers of upcoming clinical reviews via certified mail return receipt requested as described in ITB Section 2.1, item 15.

# **Preferred Drug Program**

ITB 2.3 #9. Provide clinical reviews upon request by Medicaid for coverage, PA determination, override determination, or clinical intervention on drugs or drug classes that fall outside the scope of the PDL and the P&T Committee, not to exceed 2 requested reviews per year as described in Section 2.1, item(s) 29, 31, 34. Potential reviews may include ALGI review on drug file and vitamin/mineral review for coverage.

GHS will provide clinical reviews upon request by Medicaid for coverage, PA determination, override determination, or clinical intervention on drugs or drug classes that fall outside the scope of the PDL and the P&T Committee as described in ITB Section 2.1, items 29, 31, and 34.

ITB 2.3 #10. Provide queries to identify AHFS classes and subclasses for review or potential edits. Provide projected cost savings on these groupings based on past claims data, projected utilization shifts, and any other clinical or financial data as described in Section 2.1, item(s) 25, 29, 31, 34.

GHS will provide queries to identify AHFS classes and subclasses for review or potential edits. GHS will provide projected cost savings on these groupings based on past claims data, projected utilization shifts, and any other clinical or financial data as described in ITB Section 2.1, items 25, 29, 31, and 34.

ITB 2.3 #11. Provide timely notification in writing to Medicaid staff for drugs that are eligible for review or PA as described in Section 2.1, item(s) 25, 34.

GHS will provide timely notification in writing to Medicaid staff for drugs that are eligible for review or PA as described in ITB Section 2.1, items 25 and 34.





ITB 2.3 #12. Provide electronic versions and maintain all PDL lists to include: PDL final posting, PDL by Therapeutic category, PDL by alphabetical order, PDL Reference Tool. PDL documents are updated after each P&T clinical review and on a quarterly basis. Medicaid must approve all drafts and will notify Contractor of deadlines associated with lists as described in Section 2.1, item(s) 24.

GHS will provide electronic versions and maintain all PDL lists to include: PDL final posting, PDL by therapeutic category, PDL by alphabetical order, and PDL Reference Tool. PDL documents are updated after each P&T clinical review and on a quarterly basis. GHS will provide drafts for Medicaid approval and will follow all deadlines associated with lists as described in ITB Section 2.1, item 24.

ITB 2.3 #13. Provide internal and external criteria as relates to drug classes for review for PDL and on prior authorization as described in Section 2.1, item(s) 28. New or updated criteria must be consistent with current criteria and must be approved by Medicaid. Criteria is developed at the time of the PDL review or edit implementation, final draft is to be approved by Medicaid based on Commissioner approval, and is updated only if needed. Criteria already developed by Medicaid at the time of the writing of this ITB will be updated only if need should arise.

GHS will provide internal and external criteria as related to drug classes for review for PDL and on Prior Authorization as described in ITB Section 2.1, item 28. GHS will ensure that new or updated criteria will be consistent with current criteria and will be submitted to Medicaid for approval.

ITB 2.3 #14. Upon implementation of the contract, Contractor shall review and analyze Medicaid's operational policies and procedures related to the Preferred Drug Program as described in Section 2.1, item(s) 27. Within 6 months of the implementation of the contract, Contractor shall provide in writing to Medicaid its analysis and recommendations for changes/improvements.

Upon implementation of the contract, GHS will review and analyze Medicaid's operational policies and procedures related to the Preferred Drug Program as described in ITB Section 2.1, item 27. GHS will provide in writing to Medicaid its analysis and recommendations for changes/improvements within 6 months of contract implementation. GHS performs a similar process in Iowa where we assist in updating the pharmacy provider manual and revising the P&T Committee policy and procedures handbook.

ITB 2.3 #15. Provide electronic spreadsheets to determine brand versus generic drugs to be reviewed using Medicaid approved methodology as described in Section 2.1, item(s) 30 to include: RedBook data, Orange Book data, and manufacturer data. Notify Medicaid in the event drugs need to be modified with First DataBank regarding brand versus generic designation.

GHS will provide electronic spreadsheets to determine brand versus generic drugs to be reviewed using Medicaid approved methodology as described in ITB Section 2.1, item 30 to include: RedBook data, Orange Book data, and manufacturer data. GHS will notify Medicaid in the event drugs need to be modified with First DataBank regarding brand versus generic designation.





ITB 2.3 #16. Provide identification of single versus combination products when requested by Medicaid as relates to queries, reviews, projected cost savings, criteria, clinical or financial inquiries as described in Section 2.1, item(s) 3, 25. Make recommendations to Agency when requested regarding single versus combination products.

GHS will provide identification of single versus combination products when requested by Medicaid as related to queries, reviews, projected cost savings, criteria, or clinical or financial inquiries as described in ITB Section 2.1, items 3 and 25. GHS will make recommendations to the Alabama Medicaid Agency when requested regarding single versus combination products.

ITB 2.3 #17. Provide the maximum unit list using methodology approved by Medicaid in electronic format, with all additions/changes identified as described in Section 2.1, item(s) 32. This list should be updated on a biweekly basis according to a timeline approved by Medicaid. New drugs identified for classes already implemented to the max unit list must be approved by or recommended by Medicaid. All additions/changes should be supplied to Medicaid in a separate electronic spreadsheet, in a format approved by Medicaid to include such criteria as drug name, strength, NDC, and GCN so that these updates can be coordinated with First DataBank. Additional drugs classes are added to maximum units list when reviewed for PDL.

GHS will provide the maximum unit list using methodology approved by Medicaid in electronic format, with all additions / changes identified as described in ITB Section 2.1, item 32. This list will be updated on a biweekly basis according to a timeline approved by Medicaid. New drugs identified for classes already implemented to the maximum units list will be approved by or recommended by Medicaid. All additions/changes will be supplied to Medicaid in a separate electronic spreadsheet, in a format approved by Medicaid to include such criteria as drug name, strength, NDC, and GCN so that these updates can be coordinated with First DataBank. Additional drugs classes are added to maximum units list when reviewed for PDL.

ITB 2.3 #18. Upon request by Medicaid, provide recommendations for appropriate coverage or non-coverage of nutritional products using a methodology approved by Medicaid. Contractor will analyze all products to be reviewed and make recommendations to place products on the covered or non-covered list using a methodology approved by Medicaid as described in Section 2.1, item(s) 33. Such requests will not exceed once per quarter.

Upon request by Medicaid, GHS will provide recommendations for appropriate coverage or non-coverage of nutritional products using a methodology approved by Medicaid. GHS will analyze all products to be reviewed and make recommendations to place products on the covered or non-covered list using a methodology approved by Medicaid as described in ITB Section 2.1, item 33.

GHS will reference CMS' policies on coverage or non-coverage of nutritional products in addition to the methodology approved by Medicaid.





ITB 2.3 #19. Review weekly the FDB Clinical and Editorial Highlights and provide recommendations of needed action to Medicaid as described in Section 2.1, item(s) 29, 30. Examples include: AHFS classification updates and how these changes may impact our PDL or other edits, gender restrictions implemented by FDB, and GSN additions that may affect max unit restrictions or other edits.

GHS will Review weekly the FDB Clinical and Editorial Highlights and provide recommendations of needed action to Medicaid as described in ITB Section 2.1, items 29 and 30. Examples include: AHFS classification updates and how these changes may impact Alabama's PDL or other edits, gender restrictions implemented by FDB, and GSN additions that may affect max unit restrictions or other edits.

### General

ITB 2.3 #20. Provide staff who are available to respond to Medicaid requests in a timely manner. It is expected that all telephone calls, emails and faxes from Medicaid should be responded to within one business day. All requests for information are to be delivered within the timeframe established by Medicaid in coordination with Contractor as described in Section 2.1, item(s) 9.

GHS will provide staff who are available to respond to Medicaid requests in a timely manner. GHS will respond to all telephone calls, emails, and faxes from Medicaid within one business day. All requests for information are to be delivered within the timeframe established by Medicaid as described in ITB Section 2.1, item 9.

ITB 2.3 #21. Notify Medicaid in advance if designated Contractor staff will be unavailable or out of the office. A qualified, alternate contact is to be designated as described in Section 2.5.1.

If the designated Project Manager is unavailable or out of the office, a qualified representative from GHS will be available to perform his or her duties. GHS maintains a staff of highly qualified pharmacists and physicians who can be made available to Alabama Medicaid.

ITB 2.3 #22. Provide designated staff to participate in Medicaid/Contractor meetings/conference calls as scheduled by Medicaid in coordination with Contractor as described in Section 2.1, item(s) 4, 11, 21.

The Project Manager and appropriate clinical and administrative personnel will be available to participate in meetings and conference calls as scheduled by Medicaid.

ITB 2.3 #23. Adhere to Medicaid policies for meetings and communications with pharmaceutical industry representatives to include but not limited to those detailed in Attachment G regarding issues contained in the Scope of Work of this ITB.

GHS will adhere to the policy and procedures as detailed in Attachment G of the ITB in regards to meetings and communications with pharmaceutical industry representatives.





# Hemophilia Audit Program

ITB 2.3 #24. Develop audit procedures for the following (as described in Section 2.1.1, item(s) 1, 2, 3, 4, 13):

Each pharmacy providing hemophilia product/service

Top 10 Recipient Users (product and cost amount)

Recalled Product Analysis

Dispensed Dose Assay Analysis

Hemophilia Standards of Care Compliance

Maintaining client and provider confidentiality during audit process

As described in ITB Section 2.1.1, items 1, 2, 3, 4, and 13, GHS will develop audit procedures for the following

- Each pharmacy providing hemophilia product/service;
- Top 10 Recipient Users (product and cost amount);
- Recalled Product Analysis;
- Dispensed Dose Assay Analysis;
- Hemophilia Standards of Care Compliance; and
- Maintaining client and provider confidentiality during audit process.

ITB 2.3 #25. Request pharmacy claims records from participating providers as described in Section 2.1.1, item(s) 5, 6.

GHS will request pharmacy claims records from participating providers as described in ITB Section 2.1.1, items 5 and 6. GHS currently provides pharmacy claims records services to the States of Iowa, Maine, and West Virginia. ITB 2.3 #26. Draft audit notification and status letter templates to be sent to potentially audited providers as described in Section 2.1.1, item(s) 10.

For Medicaid approval, GHS will draft audit notification and status letter templates to be sent to potentially audited providers as described in ITB Section 2.1.1, item 10.

ITB 2.3 #27. Provide Alabama Medicaid with a listing of pharmacies to be audited as described in Section 2.1.1, item(s) 9.

With support from Alabama's DSS, GHS will provide Medicaid with a listing of pharmacies to be audited as described in ITB Section 2.1.1, item 9. ITB 2.3 #28. Provide documentation to designated Alabama Medicaid staff of each audit conducted and its outcome as described in Section 2.1.1, item(s) 7, 8.





GHS will provide documentation to designated Alabama Medicaid staff for each audit conducted and its outcome as stated in ITB Section 2.1.1, items 7 and 8.

#### General

ITB 2.3 #29. Provide staff who are available to respond to Medicaid requests in a timely manner. It is expected that all telephone calls, emails and faxes from Medicaid should be responded to within one (1) business day. All requests for information are to be delivered within the timeframe established by Medicaid in coordination with Contractor as described in Section 2.1.1., item(s) 11, 12.

GHS will provide staff who are available to respond to Medicaid requests in a timely manner. All telephone calls, emails, and faxes from Medicaid should be responded to within one (1) business day. All requests for information are will be delivered within the timeframe established by Medicaid in coordination with GHS as described in ITB Section 2.1.1, items 11 and 12.

ITB 2.3 #30. Notify Medicaid, in advance, if designated Contractor staff will be unavailable or out of the office. A qualified, alternate contact is to be designated as described in Section 2.1.1, item(s) 11.

GHS will notify Medicaid, in advance, if designated staff is unavailable or out of the office. A qualified, alternate contact will be designated as described in ITB Section 2.1.1, item 11.

ITB 2.3 #31. Provide designated staff to participate in Medicaid/Contractor meetings/conference calls as scheduled by Medicaid in coordination with Contractor as described in Section 2.1.1, item(s) 13.

GHS will provide designated staff to participate in Medicaid/GHS meetings/conference calls as scheduled by Medicaid in coordination with GHS as described in ITB Section 2.1.1, item 13.

ITB 2.3 #32. Adhere to Medicaid policies for meetings and communications with pharmaceutical industry representatives to include but not limited to those detailed in Attachment G regarding issues contained in the Scope of Work of this ITB.

GHS will adhere to the policy and procedures as detailed in ITB Attachment G in regards to meetings and communications with pharmaceutical industry representatives.

ITB 2.3 #33. Provide a Medicaid approved professional clinical representative to be present at fair hearings as described in Section 2.1.1, item(s) 13.

GHS will provide a Medicaid approved professional clinical representative to be present at fair hearings as described in ITB Section 2.1.1, item 13.





# **ITB Section 2.5 Key Personnel**

GHS will have in place the necessary personnel to perform all duties and responsibilities outlined in this ITB. GHS will bring a wealth of pharmacological experience to help Alabama Medicaid manage its P&T Committee, PDL, and Hemophilia Audit Program. Our diverse clinical staff of pharmacists and medical doctors will be available to support and assist Alabama Medicaid carry out its pharmacy services obligations.

Medicaid shall have the absolute right to approve or disapprove Contractor's and any subcontractor's staff or to require the removal or reassignment of any personnel found by Medicaid to be unwilling or unable to perform under the terms of the contract. Contractor shall, upon request, provide Medicaid with a resume/CV of any member(s) of its staff or a subcontractor's staff assigned to or proposed to be assigned to any aspect of the performance of this contract. Personnel commitments made on Contractor's response shall not be changed except as herein above provided or due to the resignation of any named individual. Any personnel of a clinical nature (i.e. pharmacist, physician, nurse, technician, etc.) must have current license and be in good standing with their respective appropriate state board.

# 2.5.1 Project Manager

Contractor shall assign a Project Manager with a minimum of an Undergraduate Degree to the Alabama Medicaid Agency contract. The Project Manager shall be the person assigned under this contract, who is responsible for operation of contract duties. Contractor shall make a good faith effort to use the same Project Manager throughout the contract. Contractor shall notify Medicaid in writing of any proposed change in Project Manager at least 30 days prior to the change. Contractor shall notify Medicaid immediately of any extenuating circumstances which would prevent Contractor from meeting the 30-day notification time frame. Contractor shall furnish with its response to the ITB a resume for the proposed Project Manager which shall include the individual's name, current address, current title and position, experience with Contractor, experience in performing relevant functions, relevant education and training, and management experience. Two work references shall also be included.

Contractor's Project Manager shall serve as liaison and shall be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel; he/she shall attend, upon request, Medicaid meetings, administrative hearings, meetings and hearings of Legislative Committees and interested governmental bodies, agencies, and officers; and he/she shall provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program. Whenever the Project Manager is not reasonably available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this section.

### 2.5.2 Clinical Pharmacist

Contractor shall assign a Project Manager with a minimum of an Undergraduate Degree to the Alabama Medicaid Agency contract. The Project Manager shall be the person assigned under this contract, who is responsible for operation of contract duties. Contractor shall make a good faith effort to use the same Project Manager throughout the contract. Contractor shall notify Medicaid in writing of any proposed change in Project Manager at least 30 days prior to the change. Contractor shall notify Medicaid immediately of any extenuating circumstances which would prevent Contractor from meeting the 30-day notification time frame. Contractor shall furnish with its response to the ITB a resume for the proposed Project Manager which shall include the individual's name, current address, current title and position, experience with





Contractor, experience in performing relevant functions, relevant education and training, and management experience. Two work references shall also be included.

Contractor's Project Manager shall serve as liaison and shall be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel; he/she shall attend, upon request, Medicaid meetings, administrative hearings, meetings and hearings of Legislative Committees and interested governmental bodies, agencies, and officers; and he/she shall provide timely and informed responses when operational and administrative issues arise in administration of the Alabama Medicaid Program. Whenever the Project Manager is not reasonably available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this section.

Contractor shall assign a Clinical Pharmacist with a minimum of a Doctor of Pharmacy degree to the Alabama Medicaid Agency contract. This person must have a current license and be in good standing with the appropriate State Board of Pharmacy. The Clinical Pharmacist shall be the person assigned under this contract, who is responsible for the clinical components of the contract duties. He/She must possess superior clinical competence and demonstrate proficiency in drug therapy management. Contractor shall make a good faith effort to use the same Clinical Pharmacist throughout the contract. Contractor shall notify Medicaid in writing of any proposed change in Clinical Pharmacist at least 30 days prior to the change. Contractor shall notify Medicaid immediately of any extenuating circumstances which will prevent Contractor from meeting the 30-day notification time frame. Contractor shall furnish with its response to the ITB a resume for the proposed Clinical Pharmacist which shall include the individual's name, current address, current title and position, experience with Contractor, experience in performing clinical functions, and relevant education and training. Two work references shall also be included.

Contractor's Clinical Pharmacist shall serve as clinical resource and shall be available and responsible, as the need arises, for consultation and assistance with Medicaid personnel; he/she shall attend, upon request, meetings relevant to the scope of work in this ITB to include all meetings of the Pharmacy and Therapeutics Committee. Whenever the Clinical Pharmacist is not reasonably available, Contractor shall provide a designated alternate fully capable of meeting the requirements of this section.

GHS has assigned Chad Bissell, Pharm.D., as the Project Manager and Clinical Pharmacist to this project. Dr. Bissell currently serves as GHS' Clinical Pharmacy Manager in Iowa in a similar capacity to the needs of this ITB as oversight and support of their P&T Committee. Dr. Bissell is a licensed pharmacist in the State of Iowa and is in the process of gaining Alabama licensure. For Iowa Medicaid, Dr. Bissell currently reviews all claims that exceed \$10,000. The majority of these (95%) are claims for hemophilia drugs. He reviews these claims and works with the prescribers' representatives to ensure the claims are for appropriate quantities of drugs consistent to the billed days supply for our quality assurance program.

GHS is experienced in establishing satellite operations away from our home office as we have in Iowa. GHS intends to hire a highly qualified Clinical Pharmacist from Alabama upon award of contract, while Dr. Bissell will remain as Project Manager. This is the model GHS used when establishing our IOWA office, where we hired local professionals to fill key roles. Our intention is for the clinical pharmacist to fulfill the role of hemophilia audit coordinator; however, we realize that such a combination of skills may be difficult to recruit and would therefore consider hiring





an RN to fill the auditor role. GHS will provide thirty (30) days notice to Medicaid of any personnel change.

#### 2.5.3 Other Personnel

This shall include: 1.) staff member with a financial-based education (accounting, statistics, business degree, etc.) for projected cost savings data and 2.) other clinical ( to include experts in specific drug class areas of respected review, i.e. mental health drugs, diabetic agents, etc.) and administrative personnel to carry out the requirements of this contract. The bid response must clearly outline Contractor's plan to address the personnel requests of this ITB.

GHS has the demonstrated ability to secure the services of professional staff/expertise to meet contract requirements. GHS will make available to the project Luc Pepin, Manager of Finance, and Dr. Ayyub Atayev, who serves as the lead Clinical Analyst in support of PDL design and enhancement for the states of Maine, Iowa, and West Virginia. Dr. Atayev also works closely with Dr. Tim Clifford and Dr. Laureen Biczak to study and define new cost saving and quality of care strategies to be implemented in the PDLs GHS maintains. Laurie Roscoe, R.Ph., our Pharmacy Manager and experienced P&T Committee member, will also provide administrative oversight and clinical support for this project. Jason Hargrove, PMP, Strategic Project Manager, will provide project management and administrative support from our Augusta, Maine, office. Curriculum vitae for listed personnel begin on page 53.

After contract award, GHS expects to establish a presence in Alabama, most likely in or near the greater Montgomery area. There may be a possibility to share an office location with other Alabama vendors; this is the situation with GHS' Iowa operational facility. Having a local presence is essential as it will allow GHS to hire Alabama residents to perform operational and management tasks related to the Alabama's clinical pharmacy services. It will also allow us to be close to state Medicaid administrators and other MMIS vendors.

On the following page, we have attached an organization chart for our assigned personnel.





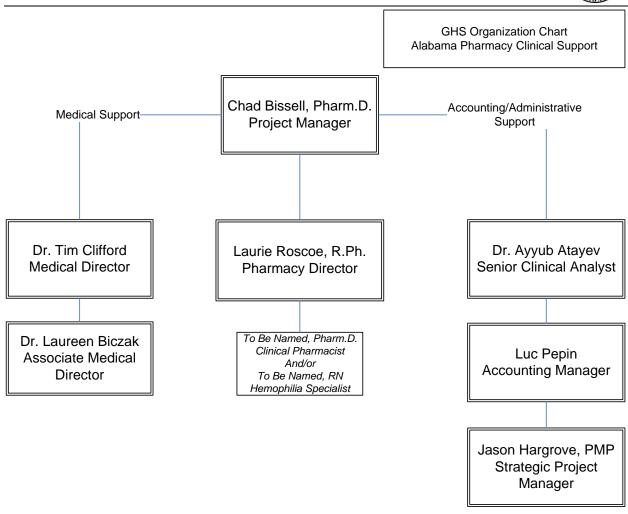


Figure 6 GHS Organizational Chart for Alabama Pharmacy Clinical Support





# **Curriculum Vitae**

### CHAD BISSELL, R.Ph., Pharm.D

# Clinical Pharmacy Manager

# **Experience:**

# 2005-Present Pharmacist / Clinical Pharmacy Manager

Goold Health Systems, Inc.

**IME Medical Pharmacy** 

100 Army Post Road

Des Moines, Iowa 50315

- Pending approval to be named as Director of the Drug Utilization Review Commission.
- Advise the Iowa Department of Human Services on a wide range of pharmacy policy issues concerning the State's Medicaid Program.
- Prepare Exception to Policy and Appeal hearings for the State and represent the Department at legal hearings.
- Facilitate the Iowa Pharmaceutical and Therapeutics Committee Meetings as part of the professional staff.
- Provide explanations to legislators and government officials on the Department's handling of specific policy issues regarding the Preferred Drug List.
- Act as the main contact person for pharmaceutical manufacturer representatives in collecting clinical data for new drug products.
- Update the Iowa Pharmacy Provider's Manual for the State of Iowa and authored the Iowa Pharmaceutical and Therapeutics Committee Policies and Procedures Manual.
- Perform case reviews for Iowa Medicaid members to enforce the Preferred Drug List by issuing prior authorizations or denials.
- Handle questions and problems from physician and pharmacy providers, as well as offer drug therapy recommendations based on the Preferred Drug List.

# 2003-2005 Staff Pharmacist

Hy-Vee Pharmacy, Pleasant Hill Pleasant Hill, Iowa

- Performed day-to-day retail pharmacy duties, including: filling
  prescriptions, minor compounding, over-the-counter consultation,
  patient counseling, interacting with other healthcare professionals,
  performing thorough drug regimen reviews, and recommending
  drug therapy changes to patients and physicians.
- Maintained volunteer efforts for the Des Moines Group, which provides health screening services and immunization clinics for community events and local businesses.





- Oversaw and provided services for Outcomes Insurance at store location.
- Administered immunizations.

### 2002-2003 Des Moines Float Pharmacist

Hy-Vee Foods, Inc.

- Fulfilled staffing needs for Des Moines area Hy-Vee and Drug Town pharmacies, as well as Hy-Vee corporate office.
- Volunteered services at health fairs, including: screenings for blood glucose, blood pressure, and osteoporosis, as well as flu shot clinics.
- Contributed to a merchandise price adjustment project with H-Vee Corporate.
- Oversaw startup of Grinnell Hy-Vee pharmacy operation and provided managerial services for first 2 months of operation.

### **Education:**

Drake University, West Des Moines, Iowa

Doctor of Pharmacy, May 2002 GPA: 3.599 Cum Laude

# Des Moines Roosevelt High School

High School Diploma, May 1996 Valedictorian.

# Professional Certifications, Qualifications, and Memberships:

Recipient of the Russ Johnson, Jr. Award for Outstanding Community Pharmacy Practice, 2002

Drake University President's List, Spring 2001

Drake University College of Pharmacy Deans List, Fall 1997, Spring 1998, Spring 1999, Fall 2000

### **References:**

Eileen Creager, Bureau Chief, Long Term Care Iowa Medicaid Enterprise 100 Army Post Rd. Des Moines, IA 50315 515.725.1273

Dr. Thomas Kline, D.O., Medical Director Iowa Medicaid Enterprise 100 Army Post Rd. Des Moines, IA 50315 515.725.1297





### **LUC J PEPIN**

### MANAGER OF FINANCE

# **Experience:**

# 1998-Present Manager of Finance

GHS Data Management, Inc., 622-7153 45 Commerce Drive, Suite 5 PO Box 1090 Augusta, ME 04332-1090

- Review daily cash activity.
- Responsible for all Monthly Financial reporting to management.
- Responsible for all Financial Forecast of Revenue and Expenses.
- Supervise and backup for all payroll functions.
- Review all general ledger account analysis in preparation for annual audited financial statement by our CPA firm.
- Supervise Accounts Receivable and billing of state contract work.
- Prepare and maintain all records for MAAP audits.

# 1993–1998 Accounting Manager

NRF Distributors, Inc Old Belgrade Road Augusta, ME

- Directed all day-to-day activities of the accounting department.
- Responsible for all general ledger activity and accounts payable function.
- Developed a professional staff through proper selection, training, and supervision.
- Monthly closing of general ledger and timely production of financial statements to management.
- Responsible for all weekly and monthly bank reports in relation to an asset based loan.

# 1990–1993 Assistant Accounting Manager (same duties as above)

NRF Distributors, Inc

#### 1986–1990 General Accountant

NRF Distributors, Inc

- Responsible for setting records for a subsidiary on Real World general ledger system.
- Wrote all weekly and monthly general ledger entries.
- Handled daily bank transfers to subsidiary in Calhoun, GA.
- Reconciled all bank accounts.

### 1981-1986 Accountant





Jean Pepin Drywall Company

- Responsible for all internal accounting functions; payroll, accounts payable, accounts receivable, and general ledger.
- Responsible for all financial reports to the owners.

### 1975-1981 Accountant

J H Shostak Builder

- Responsible for all internal accounting functions; payroll, accounts payable, accounts receivable, and general ledger.
- Responsible for all financial reports to the owners.

### **Education:**

Thomas College, Waterville, Maine Bachelor of Science, Business Administration





# DR. AYYUB R. ATAYEV, MD

# Senior Clinical Analyst

# **Experience:**

2004-Present Senior Clinical Analyst

GHS Data Management, Inc., 622-7153 45 Commerce Drive, Suite 5 PO Box 1090

Augusta, ME 04332-1090

- Provide leading expertise in development of data and statistical models; impact assessments of healthcare interventions; clinical and pharmacy prescribing practices; healthcare quality, policies and financing; research design; data and statistical analysis for existing clients in public and commercial plans in the states of Maine, Iowa, and West Virginia.
- Conduct complex and ad hoc analytic projects and provide information for high-level internal and external users; ensure completion of client requests and deliverables according to project deadlines.
- Provide substantive assistance in development and maintenance of Preferred Drug Lists (PDL) for Maine, Iowa, and West Virginia Medicaid programs; develop and conduct analyses of significant cost savings generated by PDL implementation.
- Develop and maintain Medicare Part-D formulary, pricing, beneficiary cost, and pharmacy network files for Fox Insurance Co. providing Part D benefits in Maine and New Hampshire.
- Analyze claims for billing errors, duplicate therapies, drug-drug interactions, adherence to prescribed therapies, etc.
- Develop and execute complex algorithms (packages, procedures, functions, etc.) and ad hoc queries in Transact SQL on MS SQL Server databases; perform data and statistical analysis in SQL and Excel; and use Crystal Reports and MS Access for reporting results of analyses.
- Assist in translating findings of analyses into more efficient healthcare policies and clinical and pharmacy prescribing practices.
- Develop, program, and test analytic models; conduct forecasting and time series analysis; and predict future costs and utilization, provider patterns, and response to healthcare interventions.
- Develop research agenda and design in pharmaceutical, hospital, and medical fields with the focus on outcome analysis, utilization, expenditures, access, quality, and patients' health status.
- Provide substantive input in design of databases, interface, and report tools; analyze organizational rules and information requirements and needs of clients; and respond to requests for additional data and analysis.





• Conduct QA of data loaded into data warehouse, analyze data for completeness and consistency, and ensure data integrity.

# 2001–2004 Senior Healthcare Analyst

HealthWatch Technologies, Inc. Portland, Maine

- Provided leading expertise in development of clinical and statistical models, impact assessments of healthcare interventions, clinical practices, healthcare quality, policies and financing, medical coding, research design, sampling processes, and data and statistical analysis for existing clients in public and commercial health plans in different states: Oklahoma, Washington, Colorado, West Virginia, Kentucky, and Maine.
- Analyzed healthcare policies and their vulnerability, developed clinical algorithms identifying fraud, abuse, billing mistakes, and significant recoverable payments (over \$10 million), and profiled patients and providers.
- Conducted complex and ad hoc analytic projects and provided information for high-level internal and external users; ensured completion of client requests and deliverables according to project deadlines.
- Developed technical parts of proposals, estimated resource requirements, and provided substantive input into design of project schedules for existing and prospective clients.
- Developed and executed complex algorithms (packages, procedures, functions, etc.) and ad hoc queries in PL/SQL on Oracle databases; performed data and statistical analysis and sampling processes in PL/SQL, SAS, and SPSS; and used Access for reports.
- Developed, programmed, and tested analytic models; conducted forecasting and time series analysis, predict future costs and utilization, provider patterns, and response to healthcare interventions.
- Developed research agenda and design in pharmaceutical, hospital, and medical fields with the focus on outcome analysis, utilization, expenditures, access, quality, and patients' health status.
- Provided substantive expertise and input on design of data warehouse, interface, and report tools; analyzed organizational rules and information requirements and needs of clients; and responded to requests for additional data and analysis.
- Conducted QA of data loaded into data warehouse, analyzed data for completeness and consistency, and ensured data integrity.
- Translated findings of analyses into healthcare policies and clinical practices by disseminating them to policy makers and providers.





# 2001 Healthcare Analyst

Maine Department of Health and Human Services Augusta, Maine

- Served as a technical expert to high-level clients in and outside Maine State Government on issues of disease management, healthcare quality assessment and improvement, costs, medical and drug outcomes, research design, and data and statistical analysis.
- Designed and programmed SAS codes in preparing, cleaning, and analyzing data and producing output files for reports.
- Reviewed costs, drug, and medical outcomes of the Physicians' Directed Drug Initiative; designed and conducted research and program evaluations; collected data from MMIS; and performed statistical analysis applying SAS.
- Monitored provider compliance; analyzed changes in provider behavior; and provided substantive input into development of recommendations to healthcare providers, state and federal officials, and the public.
- Disseminated research findings through reports and presentations.

### 2000-2001 Research Assistant

University of Southern Maine Portland, Maine

- Developed, revised, and modified research design, plan, and products; oversaw implementation efforts of survey staff.
- Participated in the construction of data warehouse with data derived from survey, conducted data, and statistical analysis.
- Designed and programmed SAS codes in performing research and evaluation for Maine Labor Force Analysis Project.
- Summarized research findings, prepared reports and presentations to the State of Maine and the general public.

# 2000 Planning & Research Associate II

Maine Department of Health and Human Services Augusta, Maine

- Analyzed impacts of interventions, policies, and programs in healthcare services, pharmacy, and disease management.
- Designed and performed research, assessments, and program evaluations of cost-effectiveness and quality improvement within the state Medicaid program and community healthcare services.
- Coordinated planning activities.
- Developed SAS codes in data and statistical analysis, conducted forecasting of healthcare expenditures, use and access.
- Performed data and statistical analysis, summarized financial, drug and medical outcomes of healthcare policies and interventions, prepared reports and presentations on research findings.





### 1998–1999 Medical Director

United Methodist Committee on Relief (UMCOR) Baku, Azerbaijan

- Oversaw clinical data collection efforts, development and analysis
  of survey-related databases, trained survey staff, and taught FDA
  and WHO drug and clinical guidelines to medical and pharmacy
  providers.
- Designed and maintained standard operating procedures; facilitated strategic planning activities; developed proposals, programs, implementation plans, and schedules; provided technical direction; and monitored contractors.
- Oversaw implementation of healthcare interventions and programs (worth \$4.5 million) for over 200,000 refugees and approx. 2.5 million vulnerable people, supervised 42 employees: physicians, nurses, pharmacists, and programmers.
- Analyzed and translated findings into new policies and programs, made reports and presentations to US State Department, US Agency for International Development, various UN agencies, other donors, and the public.

# 1997-1999 *Professor*

American University of Baku Baku, Azerbaijan

- Taught public health to students with a focus on healthcare costs, access and quality.
- Introduced research tools from the fields of clinical and drug research, medical sociology, demographics, and statistics.
- Analyzed and presented research findings related to healthcare problems and policies developed for their solution.

### 1997-1999 Assistant Medical Director / Medical Director

United Methodist Committee on Relief (UMCOR) Baku/Barda, Azerbaijan

- Assistant Medical Director (1998-1999):
  - Managed healthcare projects (\$2 million worth) providing medical and pharmaceutical services.
  - o Oversaw immunization, primary and institutional care to about 110,000 refugees and 4,500 handicapped children.
  - Taught FDA and WHO guidelines to medical and pharmacy providers; trained survey staff in clinical data collection and development of survey-related databases.
- Medical Director (1997-1998):
  - Oversaw clinical data collection efforts, development and analysis of survey-related databases, trained survey staff.
  - Designed and maintained standard operating procedures;
     facilitated strategic planning activities; developed proposals,





- programs, implementation plans, and schedules; provided technical direction; and monitored contractors.
- Oversaw implementation of healthcare interventions and programs (worth \$4.5 million) for over 200,000 refugees and approximately 2.5 million vulnerable people, supervised 42 employees: physicians, nurses, pharmacists, and programmers.
- Analyzed and translated findings into new policies and programs. Made reports and presentations to US State Department, US Agency for International Development, various UN agencies, other donors, and the public.

# 1996-1997 Medical Field Officer

International Committee of the Red Cross (ICRC) Baku/Barda, Azerbaijan

- Managed complex healthcare projects, provided prevention, diagnostics and treatment to war victims and refugees.
- Designed and conducted surveys, needs assessments and clinical evaluations in the region.
- Organized primary data collection efforts and survey-related databases, performed data and statistical analysis, summarized findings, prepared reports and made presentations to ICRC Field Offices and Head Quarters.

# 1990–1996 Assistant Professor

Azerbaijan Medical Institute Baku, Azerbaijan

- Provided diagnostics and treatment to various patients at hospital and outpatient clinical settings.
- Conducted research in medical and pharmaceutical fields, collected and analyzed research data, summarized and presented findings at conferences and in publications.
- Taught medical students, prepared training materials and developed training curriculum.

### **Education:**

# Harvard School of Public Health, Boston, MA

• Certificate in Measurement, Design and Analysis Methods for Health Outcomes Research, August, 2004.

# University of Southern Maine, Edmund Muskie School of Public Service, Portland, ME

 Certificate of Graduate Studies in Health Policy and Management, May, 2001





# Duke University, Center for International Development Research, Durham, NC

• Certificate of Special Program in Public Policy and Administration, October, 1999

# Azerbaijan Medical Institute, Baku, Azerbaijan

• Certificate of Clinical Residency, October, 1990

# Azerbaijan Medical Institute, Baku, Azerbaijan

• M.D. with Honors, June, 1988

# **Professional Affiliations & Memberships:**

- Member of American Statistical Association
- Author and co-author of eight articles in public health and medical research





# DR. TIMOTHY CLIFFORD, MD

### **Medical Director**

# **Experience:**

#### 2001–Present Medical Director

GHS Data Management, Inc. 45 Commerce Drive, Suite 5 PO Box 1090

Augusta, Maine 04332-1090

- Full-time Medical Consultant on drug-related issues including:
  - o Preferred Drug List development and management
  - o Supplemental Rebate strategies and management
  - o Drug rebate pool management
  - o DUR Program
  - o DUR Committee support
  - o PDDI Program studies, analyses and clinical direction
  - PA Clinical direction, determinations, savings analyses, report oversight, new target identification
  - o Recipient drug abuse
  - o Prescriber issues
  - o Maine MAC assistance
  - Drug waiver model development
  - o Drug Program presentations
  - o Drug related ad hoc requests
  - o Attorney General's Office requests

### 1996-2001 Medical Director

Bureau of Medical Services Maine Department of Human Services State House Station 11 Augusta, Maine 04330

- Full-time Medical Director for Maine Bureau of Medical Services (Medicaid Program).
  - o Provided direction in all aspects of Quality Assurance.
  - o Directed medical data analysis.
  - Consultant for policy development, prior authorizations, out of state referrals, and medical necessity determinations.
- Performed extensive analysis of heavy narcotic prescribers to identify physician outliers.
- Created Covered Services Team implementing Eddy criteria for new covered services decisions.
- Member New England Dual Eligibilities Initiative Quality and Performance Measurement Work Groups 1997–2001. Participated in analysis of integrated Medicaid and Medicare data.





- Member of Health Care Financing Administration Quality Assurance Technical Advisory Group.
- Member of National Committee for Quality Assurance Advisory Panel member for adapting HEDIS measures to fee for service populations.
- Maine Medicaid Decision Support System: assisted in development of integrated data computer system incorporating data from medical and pharmacy claims, eligibility, vital statistics, and other sources.
- Maine Medical Assessment Foundation (MMAF) Study Group participant. Collaborated on development of guidelines for CHF, Otitis Media, Asthma, and Attention Deficit Hyperactivity Disorder.
- Early Periodic Screening Diagnosis and Treatment (EPSDT).
  Replaced the obsolete one-page form with a Maine physician
  adapted set of nineteen age-specific forms directly implementing
  the Bright Futures Guidelines a standard of care supported by the
  American Academy of Pediatrics for well-child visits.
- Tobacco Prevention and Control Program Advisory Council. Appointed by Gov. Angus King, Nov. 1997–2001.
- Primary Care Physician Incentive Payment Conceptualized and implemented a quarterly payment based on relative performance across a variety of measures including panel size, access, utilization (ER), and quality preventive services. In place since 1998.
- Maine Cardiovascular Health Council Board member, unique primary / secondary CAD prevention effort underway involving multiple payers including Medicare and Medicaid.
- Child Indicators in Policy Making Partnership, co-chair 1999–2001. Selected to develop Governor's Children Committee project. Comparative measures concerned with how children are doing in the State of Maine.
- Member, HIV waiver team. Assisted in development and submission of first waiver of this type to HCFA.
- PDDI: developed voluntary physician program to promote more cost-effective prescribing by sharing data and using incentives.
- DURC: Chair of Medicaid Program Drug Utilization Committee 1999–2001, concerned with clinically appropriate prescribing and drug use safety.
- Pharmacy Advisory Group: appointed by Commissioner of DHHS to investigate methods of exerting more control over pharmacy benefit.
- Infectious Disease Work Group member- sponsored by BOH.
- Hepatitis C Work Group Member: BOH coalition concerned with improving the quality of care for Hepatitis C patients and increasing access to care.





# 1986–1996 Family Practitioner

Bucksport Regional Health Center

Bucksport, Maine

- Full-time physician. Concluded remainder of four-year N.H.S. commitment.
- Served as Medical Director from 1989 to 1996
- Quality Assurance Program Director since 1990, including tracking systems for referrals, PAP smears, mammograms, chronic hypertension, immunizations, etc.
- Medical Director of Maine Cholesterol Center, created after attending John Hopkins Lipid Training Center Program in 1993.
- Champion International Primary Care Network Plan Board physician member from 1993 to 1996.

# 1985–1986 Family Practitioner

Tri-County Health Systems

140 Norwood Rd

Warrenton, GA 30828-3107

- Fulfilled first year of National Health Service duty as primary care doctor in rural health center.
- Assistant Professor of Medicine for Medical College of Georgia with instruction of medical students and family practice residents.
- Served on Georgia Hypertension Committee in 1986.

# 1982-1985 Maine Dartmouth Family Practice

Augusta, ME

• Internship / Residency, Family Practice

### **Education:**

# Boston College, Boston, MA

Dates Attended: 9/1974-5/1978

B.A., Psychology, May 1978, Summa Cum Laude, Phi Beta Kappa

Research Assistant. 3 years, Joseph J. Tecce, Ph.D.

Co-author of several papers, including:

- "CNV Rebound and Aging. II. Type A and B CNV Shapes"
- "CNV and Myogenic Functions: II. Divided Attention Produces a Double Dissociation of CNV and EMG"

### Tufts University School of Medicine, Boston, MA

Dates Attended: 9/1978-5/1982

MD, May 1982

### Professional Licenses, Certifications, and Memberships:

Board Certification, July, 1985: Diploma, American Academy of Family Physicians

Member, American Association of Family Practice

Member, American Heart Association

Member, Maine Medical Association





# DR. LAUREEN BICZAK, D.O.

#### Associate Medical Director

# **Experience:**

#### 2007-Present Associate Medical Director

GHS Data Management, Inc. 45 Commerce Drive, Suite 5 PO Box 1090 Augusta, Maine 04332-1090

# 2005-2007 MeCMS Project Co-Lead

Maine Department of Health and Human Services State House Station 11 Augusta, Maine 04330

Served as project co-lead for remediation of the State's MMIS system

### 2000-2007 Medical Director

Maine Medicaid (MaineCare)

- Medical Director for the Maine Bureau of Medical Services (Medicaid Program).
  - Participated as a member of the Senior Management Team and was actively involved in all aspects of health care management activities including benefit design, pay for performance initiatives, budgetary issues, interpretation of Federal Medicaid law, and quality projects
  - Consultant for coverage and medical necessity determinations, prior authorization and development of agency rules
  - Consultant for policy development, as well as coding and reimbursement determinations
  - o Served as the medical expert in the development of waivers
  - o Communicated frequently with CMS and other States on a wide range of issues regarding MaineCare
  - Served as the liaison for the Department with professional associations, often publicly speaking at meetings and conventions on the Department's behalf
  - Responded on behalf of the Commissioner of Health and Human Services and the Governor to concerns and complaints from providers, legislators, and members
  - Testified at legislative hearings when requested by the Commissioner
  - Developed reports to support quality and programmatic activities





- Participated in multiple quality related workgroups and Committees
- Served as a voting member of the Drug Utilization Review Committee
- Chaired Covered Services Team
  - Reviewed new services for coverage determinations and budgetary implications
- Created Code Committee which oversaw decision analysis around new or changed codes and dealt with complex coding issues

# 1996-present Maine Medical Center Infectious Disease Teaching Service

 Actively involved in teaching students, interns, residents and fellows (including Infectious Disease Fellows) in the clinical setting

# 1990-present Clinical Practice-Office and Hospital Based

• Internal Medicine and Infectious Diseases

### **Education:**

# 1988–1990 University of Connecticut, Farmington, CT

- Clinical and Research Fellow, Infectious Disease Program
- Program Director: Sam T. Donta, MD

# 1986-1988 Osteopathic Hospital of Maine, Portland, ME

- Internal Medicine Residency
- Program Director: David A Weed, DO

# 1985-1986 Osteopathic Hospital of Maine, Portland, ME

- Rotating Internship
- Program Director: Jon Karol, DO

# 1981–1985 University of New England College of Osteopathic Medicine

- Doctor of Osteopathy
- Appointed to Sigma Sigma Phi (Osteopathic Honor Society)

# 1978–1981 University of Maine at Orono

- B.A., Zoology, Summa cum Laude
- Appointed to Phi Beta Kappa

### Professional Licenses, Certifications, and Appointments:

Chief of Staff, 1995–1997, Brighton Medical Center Chief of the Department of Medicine, 1993–1995 Brighton Medical Center Institutional Review Board Member, 1993–1995, Brighton Medical Center Staff Executive Committee Member, 1993–1997, Brighton Medical Center Chair, Infection Control Committee, 1990–1997, Brighton Medical Center





Chair, Medical Quality Review Committee Member, 1995–1997,  $Brighton \ Medical \ Center$ 

Clinical Monitoring Committee Member, 1990–1997, Brighton Medical Center Chair, Antibiotic Agents SubCommittee Member, 1990–1993, Brighton Medical Center

Library Monitoring Committee Member, 1996–1997, Maine Medical Center Physician's Information Services Committee, 1998–1999, Maine Medical Center Pharmacy and Therapeutics Committee, 1998–2002, Maine Medical Center Maine Quality Forum Advisory Committee Member, 2005–Present State of Maine, License #1167, Expiration 07/31/08

American Osteopathic Board of Internal Medicine, Internal Medicine, 03/1990, Certificate # 1013; Infectious Disease, 1991

# **Research Projects:**

HIV Infection and Endocarditis: 1989–1990, presented at International AIDs
 Conference; San Francisco, CA

 Murine CMV Infection: Published, <u>Journal of Infectious Disease</u>; citation available upon request

# **Professional Memberships:**

American College of Physicians
Maine Osteopathic Association
American Osteopathic Association
Maine Medical Association
Infectious Disease Society of America
American Society for Microbiology
HIV Medicine Association
Northern New England Infectious Disease Society
Southern Maine Osteopathic Medical Group





# LAURIE ROSCOE, R.PH.

# **Director of Pharmacy Programs**

# **Experience:**

# 2008-Present Director of Pharmacy Programs

GHS Data Management, Inc., 622-7153 45 Commerce Drive, Suite 5 PO Box 1090 Augusta, ME 04332-1090

- Project director for Medicaid Point-of-Sale prescription claims processing and private-sector contracts.
- Perform analysis of drug formularies for various public and private prescription drug plans.
- Design and analysis of retrospective drug utilization review reports.
- Coordinate the design, development, and implementation of various projects, including Medicare Part D.
- Manage the growth and maintenance of public and private-sector contracts.
- Perform clinical review of prescription drug products with regard to their safety, efficacy, and cost effectiveness.
- Maintain a complete understanding of federal and state rules and regulations concerning both public and private prescription drug plans.

# 2002-Present Chairman, MaineCare (Medicaid) Drug Utilization Review Committee

State of Maine, Bureau of Medical Services

- Chairman of the State of Maine Medicaid Drug Utilization Review (P&T) Committee 2004—present, participating member since 2002.
- DUR Committee responsible for developing and maintaining the MaineCare Preferred Drug List (PDL) and Rx benefits, analyzing data to identify opportunities for improving clinical care, and developing programs that improve the quality of pharmaceutical care for MaineCare members.

# 2004–2008 Pharmacy Program Director

Anthem BCBS, Maine

- Accountable for Anthem BCBS, Maine pharmacy benefits, including all aspects of quality, cost of care and access.
- Provided pharmacy management support to all areas of the health plan including; Cost of Care, Finance, Sales and Marketing, Actuarial, Provider and Member appeals, Customer Services, Underwriting, Provider Contracting, Government/Legislation and Care Management.





- Responsibilities included RFP oversight, finalist presentations, providing benefit/claims analysis and consulting services to external group clients to optimize pharmacy benefits and improve clinical outcomes and cost trends.
- Pharmacy sales lead consultant for the East region (CT, GA, ME, NH, NY, VA). Primary sales associate for MyHealth Advantage Program, Anthem's care management program that analyzes integrated data to identify cost-saving opportunities and discrepancies between actual care and best clinical practice. Actionable information is then communicated to members, providers, and care managers with the goal of changing member and provider behavior.
- Negotiated favorable pharmacy and medical terms for Anthem BCBS resulting in a new 3-year contract for a 40,000 member group.
- Represented New England health plans and PBMs as speaker and panel discussion member at the annual 2005 New England Employee Benefits Council conference for brokers and employer groups.
- Awarded 2006 Star Performer Award by Anthem BCBS for providing outstanding support to Sales and Maine clients.
- Maine's Unfair Prescription Drug Practices Act. Led crossfunctional team of PBM and health plan associates to develop and implement strategy to comply with State rebate law and mitigate \$30 million in liability to Anthem.
- Maine's Public Purchasing and anti-PBM legislation. Worked with large group clients, Anthem's Government Relations Dept and the Maine Legislature to successfully defeat legislation that would negatively impact Anthem.
- Responsible for \$10 million in annual cost of care savings including recontracting pharmacy networks and increasing generic dispensing rates.
- Project lead for GenericSelect, an initiative to increase the use of generic medication in all 14 Anthem states. Worked collaboratively with all areas of the PBM and health plan; including claims, customer service, finance, marketing, and sales, from initiation to client rollout.
- Led company-wide initiative to develop and implement Evidence Based Benefit Designs to increase medication compliance, increase participation in disease management programs, and improve medical outcomes.
- Team Lead for Pharmacy Program Directors across the Anthem/WellPoint enterprise.
- Presented Anthem's Evidence Based Benefit Designs at AHIP 2007 Conference.





- Participated in health plan executive-level strategic planning sessions.
- Department lead for health plan Pharmacy Department of data analysis, pharmacy service coordinators, and account managers.

### 2002-2004 Clinical Account Pharmacist

Anthem BCBS, Maine/New Hampshire

- Designed and implemented provider contracting initiatives giving financial incentives to physicians to increase overall generic utilization and improve quality of care through appropriate prescribing practices.
- Designed generic prescribing methodology for Anthem East's PCP Quality Incentive Program.
- Provided Maine physicians and organized medical groups (IPAs/PHOs) with evidence-based clinical drug information, nationally recognized treatment guidelines, new drug reviews, and group/individual data analysis to identify target areas for improvement.

# 1998–2002 Director of Pharmacy, Mt. Auburn Cambridge IPA and Deaconess Walthom PHO

CareGroup Provider Service Network (PSN)

- Managed full pharmacy risk for 85,000 managed care patients for a 700-member physician contracting entity representing physicians from Mount Auburn Hospital, Cambridge Hospital, and Somerville Hospital that negotiated preferred rates and capitated contracts with HMOs. Responsible for utilization reporting, physician profiling, individual physician counseling, group clinical presentations, therapeutic interchanges, formulary management, hospital and physician Pharmacy and Therapeutics (P&T) Committee, Medical Management, and clinical drug reviews.
- Achieved \$2 million in annual pharmacy surplus with 5% annual cost increases from a previous \$0.5 million annual deficit.

### 1997-1998 Managed Care Consultant Pharmacist

CareGroup Provider Service Network (PSN)

 Project manager for initial development of a pharmacy management program for a 3,000-member physician organization serving 400,000 managed care patients in 9 physician risk units and 7 hospitals, including Beth Israel Deaconess Medical Center, Lahey Clinic, and Mt. Auburn Hospital.

### 1992-1997 Managed Care Pharmacist

Merck-Medco Rx Services

• Quality Assurance pharmacist for a managed care mail order pharmacy.





• Responsibilities included pharmacy technician training, prior authorization approvals, and clinical support for the data entry department of a 55,000 prescription per week operation.

### 1991-1992 Retail Pharmacist

CVS, Massachusetts

### 1987-1991 Retail Pharmacist

Wellby Super Drug, Maine

### **Education:**

### Massachusetts College of Pharmacy, Boston, Massachusetts

Bachelor of Science, Pharmacy

### Boston College, Boston, Massachusetts

Bachelor of Science, Biology and Chemistry

### Licensure:

### Registered Pharmacist

Maine: 1987–Present; Massachusetts: 1991–Present





### JASON HARGROVE, PMP

### Strategic Project Manager

# Experience: 2005-Present

### Strategic Project Manager

GHS Data Management, Inc. 45 Commerce Drive, Suite 5 PO Box 1090

Augusta, Maine 04332-1090

- Responsible for the direction, coordination, and completion of assigned strategic projects.
- Manage and coordinate responses to RFPs working with professional and Technical staff, including writing RFP responses.
- Set deadlines, assign responsibilities, monitor, and summarize progress of projects.
- Supervise administrative office staff and technical writer.

### 2004-2005 Senior Mechanical Engineer

Ingersoll-Rand, Portsmouth, NH

- Team Leader, Laboratory Operations & Reliability.
- Managed all microturbine laboratory operations, test engineering, lab prioritization, supervision of mechanical technicians, and coordination of test personnel.
- Managed all microturbine reliability efforts through matrixed team
- Oversight of five direct reports, both degreed and non-degreed.

### 2002-2004 Mechanical Engineer III

Ingersoll-Rand, Portsmouth, NH

- Created project plans and provided daily management and guidance of both lab and engineering personnel to ensure timely completion of assigned tasks.
- Project Manager MT Reliability: Directed company-wide reliability efforts to deal with issues relating to new product development, with an average project team of 7–8 people.
- Project Manager 50Hz MT250: Developed a 50Hz version of the standard product based on the initial design, including project management of a new 50Hz gearbox design.
- Certification and Code Adherence: Worked with engineering and UL to successfully list IRs 70kW product.

### 2001-2002 Mechanical Engineer II

Ingersoll-Rand, Portsmouth, NH





- Managed all aspects of the Grid-Independent program from testing to production.
- Coordinated with electrical group, production, sourcing, and others to ensure project objectives were reached.
- Guided mechanical and electrical engineering teams with a focus of product listing in Q2/3 2002.
- Tested and reviewed new MT70 mechanical systems to ensure product reliability.
- Served as the Test Lab engineering focal point for test requests and new product development.
- Worked with marketing to solve customer specific issues by designing custom sub-systems.

### 1998–2001 Mechanical Engineer I

Ingersoll-Rand, Portsmouth, NH

- Completed the design, selection, and directed assembly of a new lubrication and starter system.
- Directed testing of natural gas compressor component rig.
- Managed the operation of a microturbine refrigeration unit, developing test plans and operation
- Wrote new code and modified existing data reduction code for all lab units.
- Used Pro-Engineer to develop small parts and for basic assemblies.

### 1997-1998 Jr. Engineer

Ingersoll-Rand, Portsmouth, NH

• Performed a variety of basic engineering tasks, which included the design and testing of a hydraulic starter, a high-pressure hydraulic tank, and other entry-level assignments.

#### **Education:**

### Maine Maritime Academy, Castine, Maine

Dates Attended: 1991-1995

B.S., Marine Engineering Operations, 1995

### Professional Qualifications, Certifications, Memberships:

Project Management Professional (PMP), 2004, Project Management Institute



## 6 Corporate Capabilities and Commitments

## **Corporate History**

Founded in 1974, GHS has over three decades of experience in Medicaid healthcare data management. The largest portion of our work is providing pharmacy benefit administration services, including claims adjudication, drug utilization review, and focused clinical pharmacy consultation. We also offer reporting and analysis to support state and legislative needs, standard and ad hoc reporting, help desk services, technical assistance, training, and recently added a multi-state rebate-pooling program.

Our current core services include:

- Pharmacy Benefit Services Administration (PBSA) and related services:
  - Medicaid PBSA for state programs
  - o GHS/Rx: PBSA for self Insured employers;
- A Prescription Drug Monitoring Program;
- Help desk services;
- Modern and secure data center facilities;
- Data capture and online storage:
  - o Forms Processing
  - o Document Imaging and Archiving; and
- Mailroom services outsourcing.

All of the above services are configured or customized to meet the individual needs of our clients; in many cases we constructed new systems from the ground up within very tight development timeframes. GHS is continuously looking to expand the services we offer, challenge our employees, and provide value and expertise to our clients.

GHS is a leader in Medicaid healthcare data processing. Our services include Pharmacy Benefit Services Administration with on-line, real-time pharmacy claims adjudication, drug utilization management, CMS and Supplemental Rebate management, Preferred Drug List management, P&T Committee support, focused clinical pharmacy services, Prior Authorization, and other related programs. We also offer reporting and analysis (standardized and ad hoc), help desk services, technical assistance, training, and recently helped form and manage the Sovereign States Drug Consortium (SSDC), a multi-state rebate pooling program. GHS brings over 34 years of claims processing experience to our clients and business partners. This includes 17 years of electronic Point of Sale (POS) claims processing, 12 years of drug rebate management, 7 years of PDL maintenance, and 7 years of PA experience.



## **Current Contracts and Capabilities**

Goold Health Systems has assisted the State of Maine in its electronic administration of pharmacy programs since 1991, accepting claims data for on-line adjudication for Maine's Low Cost Drugs for the Elderly and Disabled (DEL) program. In the earliest years of the DEL contract, starting in 1974, the system relied exclusively on paper claims. In 1991, GHS migrated to a fully electronic system, resulting in significant cost savings for the State at the time. In December of 1995, GHS implemented an electronic pharmacy Point of Sale (POS) claims adjudication system (MEPOP) for Maine's Medicaid pharmacy program. While not without its challenges, the development, implementation, refinement, and on-going administration of the system has proceeded with few difficulties. The services we now provide as part of the MEPOP contract include Pharmacy POS claims adjudication, PA, PDL maintenance, drug rebate management, a pharmacy / provider help desk, and other related services.

GHS operates an Intensive Benefit Management program and a Pain Management Program for the State of Maine. Both programs monitor usage of prescription narcotic medications to high-risk patients. The programs use PA on all controlled prescriptions and can force doctor and/or pharmacy choice upon historically risky patients. Random pill counts and toxicology tests are used to determine if medications are being used appropriately and legally. GHS manages and analyzes these audits and reports the results back to Maine's Medicaid program.

In the State of Iowa, we have recently developed and implemented PDL, PA, Supplemental Rebate, and pharmacy POS claims adjudication services. In 2004, GHS designed and developed a PDL and pharmacy PA system for the State's Iowa Medicaid Enterprise (IME) project. We are a subcontractor for the Medical Services portion of the project. Immediately after contract initiation, GHS commenced working with Iowa's P&T Committee, developing the PDL and negotiating Supplemental Rebates with drug manufacturers. On January 15, 2005, GHS implemented a full PDL and took over all pharmacy PA determination responsibilities from the incumbent contractor. This included the deployment of our redesigned PA determination application, PADSS 3.0, which was implemented almost six months ahead of schedule.

The second portion of GHS' work for IME began in December 2004 when we were awarded the pharmacy POS contract. As with the PA system, we upgraded our POS claims adjudication system (to version 5.1) to meet the IME requirements. We also started claims processing ahead of schedule, to ensure a smooth transition between POS vendors. The rest of the IME project became operational on June 30, 2005.

GHS also offers a private sector Pharmacy Benefit Service Administration (PBSA) called GHS/Rx, which is a prescription benefit plan available to companies with self-insured medical programs. The GHS/Rx program provides prescription drug services through a national network of pharmacies. When a GHS/Rx contract is



initiated, our pharmacists work to identify cost-effective generic equivalents of expensive drugs without sacrificing quality or integrity. There is also a drug review option that makes optimal use of current advances in drug therapies that keep participants healthier and could lower the incidence of hospitalizations.

In the fall of 2005, GHS participated in the design and became the negotiating vendor for a multi-state drug rebate pooling program, now known as the Sovereign States Drug Consortium (SSDC). The objective was to create a pool that would be attractive to states with a desire to take an active role in rebate negotiation and / or retain a higher degree of control. To encourage participation, the pool was designed to be as efficient and inexpensive as possible for participating states, while allowing the retention of current Pharmacy Benefit Management (PBM) service vendors, if desired. The initial pool states consisted of Vermont, Iowa, and Maine. In 2007, Utah joined the pool with Wyoming and West Virginia planning to join in 2008.

GHS began providing the State of Wyoming with Supplemental Rebate and Preferred Drug List services in October 2007. We are in discussions with the State to provide a complete rebate service solution. Current and planned rebate functionality will seamlessly integrate into the overall Pharmacy Benefits Management program for Wyoming.

GHS was recently hired to design West Virginia's Preferred Drug List (PDL), perform supplemental rebate negotiations, and to perform State Maximum Allowable Cost (SMAC) services. We are currently reviewing half of West Virginia's PDL, 33 drug classes, with the State's P&T Committee.

## **Corporate Commitment**

Goold Health Systems will work with the Alabama Medicaid Agency to fulfill the objectives of this ITB. Through our proven history and experience in both clinical and technical administration of pharmacy programs, we have the resources to meet the needs of Alabama Medicaid and the people it serves. GHS will provide a health and advantageous working relationship with Medicaid to improve services while minimizing costs.



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## 7 Bidder's Understanding of Alabama Requirements

GHS has a full understanding of the extent of commitment needed to fulfill our obligations. We will call upon our highly skilled staff of pharmacists, pharmacy technicians, physicians, analysts, programmers, network staff, trainers, and others to address the challenges that exist in the administration of this complex, multifaceted program. The core values of the GHS team include accountability, integrity, innovation, and commitment to community. GHS employees derive this commitment and dedication from years of providing excellent service to our clients. We have witnessed the outcomes of our services and have seen how they affect the economy, communities, and people lives.

The Alabama Medicaid Agency requires an efficient, clinically experienced, and reliable contractor for this work. GHS has proven experience in building and maintaining PDLs and in supporting P&T Committees. We have auditing tools in place and an experienced clinical team to analyze, interpret, and distribute the data we collect. As proven in this ITB response and attested to by our references, GHS can fulfill the contract requirements. Although not a specific requirement of this ITB, GHS encourages Alabama Medicaid to look into joining the SSDC, where Alabama Medicaid can enjoy greater options with services required by this ITB.

Participating in the Sovereign States Drug Consortium (SSDC) supplemental rebate pool is a great opportunity for Alabama. GHS has operated a PDL for Maine since 2003 and for Iowa since 2004. GHS worked with Maine, Iowa, and Vermont to form the SSDC Medicaid drug pool in 2005. Since then, we have performed two complete annual pool negotiations and have three additional member states, Utah, West Virginia, and Wyoming.

After reviewing our proposal, we hope Alabama Medicaid Agency pharmacy administrators will agree that working with GHS as part of the SSDC supplemental rebate pool will allow the State to achieve the greatest degree of independence and control, while optimizing savings and minimizing overhead costs. GHS' expert staff is project-oriented and is prepared to guarantee Alabama that all of our deliverables will be met in a timely manner through performance-based contract metrics.

Representing the SSDC, GHS negotiates the most advantageous contracts for the preferred drugs already listed on an SSDC member's PDL. We can also seek to provide a number of potentially superior contracts for drugs not on a PDL if an SSDC member and its P&T Committee are in favor of accepting. Although the pool negotiates prices and conditions, each state within the SSDC determines the composition of its own PDL, choosing which contracts to accept and which to reject. Alabama will retain complete PDL autonomy if it joins the SSDC pool. While in most cases the states in the pool have reached consensus and acted in unison, there were several PDL categories where one state wanted to pursue a much more or less



aggressive approach than the other partners. Maintaining this autonomy is crucial to the long-term success of the pool. In the long-term, however, savings can be maximized by all states within the SSDC synchronizing their PDLs. States must sometimes forgo immediate and specific savings to retain provider and political support.

GHS is fully capable and experienced in providing support to (P&T) Committees. We are also skilled at providing expertise when analyzing the financial and clinical impact of non-cash services (Value Added agreements).

In summary, GHS will carry out all contract responsibilities in the same highly professional, successful manner to which all our clients have become accustomed. We will look to the successful working relationships we have built in other states to ensure that Alabama receives unparalleled service and support. The transition from one contract period to the next will be seamless and without impact on providers, clients, or Alabama Medicaid itself.



## 8 Three References

### Iowa Medicaid Enterprise

Eileen Creager Bureau Chief Iowa Medicaid Enterprise 100 Army Post Road Des Moines, IA 50315

Phone#: 515.725.1273

E-Mail: ecreage@dhs.state.ia.us

#### **Bureau for Medical Services**

Peggy King, R.Ph. Director, Pharmacy Services 350 Capitol Street, Room 251 Charleston, WV 25301

Phone#: 304.558.5976 pking@wvdhhr.org

## Governor's Office of Health Policy and Finance

Jude Walsh Special Assistant Office of the Governor 15 State House Station Augusta, ME 04333-0001

Phone#: 207.624.9844 jude.e.walsh@maine.gov



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## 9 Submission of Firm and Fixed Bid Price

Monday, May 19, 2008

State of Alabama Division of Purchasing RSA Union Building 100 N. Union Street Suite 192 Montgomery, Alabama 36130-2401

Dear Mr. Arant,

On behalf of Goold Health Systems, Inc. (GHS), I am pleased to present our **Firm** and **Fixed Bid Price in response to the Invitation to Bid (ITB) # 08-X-2192281.** I am responsible for the costs being offered in our proposal and have not, and shall not, participate in any action contrary to the statements and certifications made elsewhere in this proposal.

GHS understands that this is a firm fixed price for an initial period of 12 months, with Medicaid having the opportunity to renew the contract annually at the same price as the previous period.

**<u>Firm Fixed Bid Price:</u>** Base Year 1 and Optional Years (3)

Current services: \$150,000

Expanded Hemophilia services: \$120,000

Rate Per Year Total: \$270,000 \*entered in Price Sheet

GHS will carry out all contract responsibilities in the same highly professional and successful manner which all our clients have become accustomed to receiving. Please contact me should you have any questions or need additional information. Thank you for your consideration of our proposal.

Sincerely,

James A. Clair Chief Executive Officer GHS Data Management 45 Commerce Drive, Suite 5 P.O. Box 1090 Augusta, Maine 04332

207-622-7153 207-242-2715 (cell) 207-623-5125 (fax) jclair@ghsinc.com (email)



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# 10 Appendices

# **Appendix 1: Definitions of Common Acronyms**

TERM / ACRONYM	DEFINITION
ACE / ACEI	Angiotensin Converting Enzyme Inhibitor
ADAP	AIDS Drug Assistance Program
AHRQ	Agency for Healthcare Research and Quality
ARB	Angiotensin Receptor Blocker
CMPS	Clinical Management Pharmacy Services
CMS	Centers for Medicare & Medicaid Services
DEL / MEDEL	Maine Low Cost Drugs for the Elderly and Disabled program
DSS	Decision Support System
DUR	Drug Utilization Review
FDB	First DataBank
FUL	Federal Upper Limit
GHS	GHS Data Management; Goold Health Systems, Inc.
GSN	Generic Sequence Number
HIPAA	Health Insurance Portability and Accountability Act
IME	Iowa Medicaid Enterprise
ITB	Invitation to Bid
MaineCare	Maine's Medicaid Program
MEPOP	Maine Pharmacy Point of Purchase system
MIS	Management Information Systems
MITA	Medicaid Information Technology Architecture
MMIS	Medicaid Management Information System
MSP	Multi-State Pool
NABP	National Association of Boards of Pharmacy
NASPER	National All Schedules Prescriptions Electronic Reporting Act
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
NPI	National Provider Identifier
OMS	Office of MaineCare Services (State of Maine Medicaid staff)
OSA	Maine Office of Substance Abuse
OTC	Over the Counter
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PADSS	Prior Authorization Decision Support System
PBM	Pharmacy Benefit Management
PBSA	Pharmacy Benefit Services Administration
PDDI	Physician Directed Drug Initiative
PDE	Prescription Drug Eligibility
PDL	Preferred Drug List



## Appendices

TERM / ACRONYM	DEFINITION
PDMP	Prescription Drug Monitoring Program
PDP	Prescription Drug Plan
PERM	Payment Rate Error Measurement
PMP	Prescription Monitoring Program
PMP	Project Management Plan
ProDUR	Prospective Drug Utilization Review
POS	Pharmacy Point of Sale
PPI	Proton Pump Inhibitor
RetroDUR	Retrospective Drug Utilization Review
RDL	Reference Drug List
ROSI	Remittance of State Invoice
RPC	Random Pill Count
SCM	Software Configuration Management
SMAC	State Maximum Allowable Cost
SPAP	State Pharmaceutical Assistance Program
SR	Supplemental Rebate
SSDC	Sovereign States Drug Consortium



## **Appendix 2: Mandatory Bid Requirements Checklist**

1. Has company had business license for minimum of three years?

Yes. GHS has been in business since 1974.

2. Is company licensed to do business in Alabama?

Yes, tentatively. GHS has applied for a license to conduct business in Alabama.

3. Did bidder submit original and five copies of bid and an electronic copy on CD?

Yes. We submitted one original and five copies and a Word file on CD.

4. Were all requirements specified by the ITB provided?

Yes. All requirements specified by the ITB were provided.

5. Does the bid cover the time period specified?

Yes. The bid covers the first year and provides for extensions for another three years.

6. Does the bid accept the requirement for a performance bond?

Yes. The bid accepts the requirement of a performance bond.

7. Is the bid accompanied by a bid guarantee for five thousand dollars (\$5,000)?

Yes. GHS enclosed a bid bond guarantee for \$5,000 as a bid guarantee.

8. Does the price sheet state a firm and fixed price?

Yes. The price sheet states a firm and fixed price.

9. Is page 1 of ITB signed and notarized?

Page 1 of the ITB is signed and notarized and is located in Appendix 4.

10. Was overview of company history and structure provided, as well as a description of the organization's overall capabilities?

Yes. GHS corporate overview can be found in both the Executive Summary and in the Corporate Capabilities and Commitment sections.



11. Does the bid demonstrate the ability to secure and retain professional staff to meet contract requirements to include clinical pharmacist and project manager? Are these personnel involved in pharmaceutical detailing activities for any pharmaceutical company?

Yes. GHS has the staff needed perform all duties associated with this contract. Our clinical pharmacist will serve as the account manager. He will be supported by a project manager. We would most likely recruit Montgomery-based staff to assist in our contract operations. GHS has no personnel involved in any pharmaceutical detailing activities for any pharmaceutical company.

expertise area: P&T Committee Support

expertise area: PDL Development expertise area: Medical Auditing

12. Are resume/s included for the project manager and clinical pharmacist with the bid?

Yes. The resume for the combined project manager and clinical pharmacist is included, as well as resumes for other project and clinical staff.

13. Were a minimum of three references provided? Was client name, contact name, title, telephone number, contract type, size and duration provided? Was at least one of them from a state Medicaid Agency or other government program?

Three corporate references were provided. One is from the Iowa State Medicaid office, and another is from Maine's governor's office.

14. Does the bid demonstrate the ability to avoid real or perceived conflicts of interest?

Yes. GHS' bid demonstrates no real or perceived conflicts of interest.

15. Does the bid demonstrate the ability to perform duties as outlined in the ITB?

Yes. GHS' bid demonstrates the ability to perform the duties outlines in the ITB.



## **Appendix 3: ITB Section 1.3 Disclosure Statement**

The following information must be provided by prospective bidders:

1. Are you an independent entity or a subsidiary or division of another company? If not an independent entity, describe the organization linkages and the degree of integration/collaboration between the organizations.

Goold Health Systems, Inc. (GHS) is an independent company affiliated with the Waldron Group of companies. There is no parent organization for GHS. GHS is a financial, stand-alone company. The Waldron Group is a diverse collection of companies that includes Goold Health Systems, Community Pharmacies, Portland Volvo, Portland Saab, Performance Motors, Waldo's Convenience Store, and the Falmouth Inn. Mr. William G. Waldron, Jr. is the President and owner of the Waldron Group. The Waldron Group provides some management services and oversight for these diverse companies.

2. List and explain any financial relationships with any pharmaceutical manufacturers.

Goold Health Systems, Inc., dba GHS, has no financial relationships with any pharmaceutical manufacturers.

3. If not owned by a pharmaceutical manufacturer, is your organization strategically aligned with a pharmaceutical manufacturer? If yes, describe the organization and linkages and the degree of integration/collaboration between the organizations.

GHS is not strategically aligned with any pharmaceutical manufacturers.

4. Provide in detail specific processes and procedures by which the Contractor will assure the avoidance of any conflict or appearance of conflicts of interest.

GHS has policies and procedures in place to avoid opportunities or appearances for conflict of interest. None of our employees work for the pharmaceutical industry nor derive any entitlements from any interaction or negotiation with pharmaceutical manufacturers.

5. Disclose all organizations, states, and health plans for which your organization is currently administering or has previously administered pharmacy benefits within the last three years. Provide organization names, contact persons, address, phone number and fax number.

Organization Name:	Maine Office of Substance Abuse
Contact Name:	Daniel Eccher, PMP Coordinator
Address:	11 SHS, Marquardt Building
	3rd Floor
	Augusta, Maine 04333-0011
Phone#:	207.287.3363
Fax#:	207.287.4334



## Appendices

Organization Name:	GHS/Rx
Contact Name:	Chris Riendeau
Address:	Sisters of Charity Health System, Inc.
	PO Box 7291
	Campus Avenue
	Lewiston, Maine 04243-7291
Phone#:	207.777.8781
Fax#:	207.777.8783

Organization Name:	Colorado Department of Regulatory Agencies
Contact Name:	Wendy Anderson, R.Ph., Program Director
Address:	1560 Broadway
	Suite 1310
	Denver, Colorado 80202
Phone#:	303.894.7754
Fax#:	303.894.7692

Organization Name:	Maine Office of Medical Services
Contact Name:	Jude Walsh, Special Assistant to the Governor
Address:	15 State House Station
	Augusta, Maine 04333
Phone#:	207.624.9844
Fax#:	207.624.7608

Organization Name:	Iowa Medicaid Enterprise
Contact Name:	Eileen Creager, Bureau Chief
Address:	100 Army Post Road
	Des Moines, Iowa 50315
Phone#:	515.725.1273
Fax#:	515.725.1010

Organization Name:	Bureau for Medical Services
Contact Name:	Peggy King, R.Ph., Director, Pharmacy Services
Address:	350 Capitol Street Room 251 Charleston, West Virginia 25301
Phone#:	304.558.5976
Fax#:	304.558.1542



## Appendices

Organization Name:	Wyoming Department of Health
	v 6 1
Contact Name:	Antoinette Brown, R.Ph.,Pharmacy Program
	Manager
Address:	6101 Yellowstone Road
	Suite 259 A
	Cheyenne, Wyoming 82002
Phone#:	307.777.6016
Fax#:	307.777.7127

Organization Name:	Sovereign States Drug Consortium
Contact Name:	Ann Rugg, Deputy Director
Address:	Vermont Agency of Human Services
	312 Hurricane Lane
	Suite 201
	Williston, Vermont 05495
Phone#:	802.879.5911
Fax#:	802.879.5919



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## **Appendix 4: Signed and Notarized Page 1 of ITB**

Please find the signed and notarized Page 1 of the ITB on the following page as well as the Terms and Conditions of the ITB.





















# **Appendix 5: Bid Bond**

The Bid Bond for \$5000 is attached on the following pages.

